Transcript of February 22, 2001 Meeting

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HEALTH CARE FINANCING ADMINISTRATION
Medicare Coverage Advisory Committee
Executive Committee Meeting

February 22, 2001

Baltimore Convention Center
One West Pratt Street
Baltimore, Maryland

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Panelists

Chairperson
Harold C. Sox, M.D.

Member at Large
Robert H. Brook, M.D., Sc.D.

Voting Members

Leslie P. Francis, J.D., Ph.D.
John H. Ferguson, M.D.
Robert L. Murray, Ph.D.
Alan M. Garber, M.D., Ph.D.
Michael D. Maves, M.D., M.B.A.
Frank J. Papatheofanis, M.D., Ph.D.
Thomas V. Holohan, M.D., F.A.C.P.
Daisy Alford-Smith, Ph.D.
Joe W. Johnson, D.C.
Barbara J. McNeil, M.D., Ph.D.

HCFA Liaison

Sean R. Tunis, M.D., M.Sc.

Consumer Representative

Linda A. Bergthold, Ph.D.

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Panelists (Continued)

Industry Representative

Randel E. Richner, M.P.H.

Executive Secretary

Constance Conrad, R.N.

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PANEL PROCEEDINGS

(The meeting was called to order at 8:35 a.m., Thursday, February 22, 2001.)

MS. CONRAD: Good morning, and welcome committee chairperson, members and guests. I am Constance Conrad, executive secretary of the Executive Committee of the Medicare Coverage Advisory Committee. The committee is here today to act upon the recommendations from the Medical and Surgical Procedures Panel meeting of October 17th and 18th dealing with electrostimulation for the treatment of wounds and sacral nerve stimulation for the treatment of urinary incontinence. The committee will also discuss comments received on the March 1st, 2000 interim guidelines designed to provide guidance to the MCAC specialty panels for evaluating effectiveness, and to discuss the future role of the Executive Committee.

The following announcement addresses conflict of interest issues associated with this meeting and is made part of the record to preclude even the appearance of impropriety. To determine if any conflict exists, the Agency reviewed the submitted agenda and all financial interests reported by panel participants. The conflict of interest

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statutes prohibit special government employees from participating in matters that could affect their or

their employers' financial interests. The Agency has determined that all members may participate in the matters before the committee today.

With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose and current or previous financial involvement with any firm whose products or services they may wish to comment on. This includes direct financial investments, consulting fees, and significant institutional support.

In view of the nature of this meeting today, particularly that there may be three opportunities for voting, I am going to stray from standard operating procedures and read the required voting statement at this time. Hopefully this will save time and disruption. Here we go.

For today's committee meeting, voting members present are Robert Brook, Thomas Holohan, Leslie Francis, John Ferguson, Robert Murray, Alan Garber, Michael Maves, Frank Papatheofanis, Barbara McNeil, Joe Johnson, and Daisy Alford-Smith. A quorum is present.

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With the exception of John Ferguson for the sacral nerve stimulation vote, no one has been recused because of conflicts of interest.

At this time I would like to turn the meeting over to Sean Tunis, who may have a few words for you.

DR. TUNIS: Well, let's see. The only words I will have is welcome, and thanks everybody for attending. I think we have an important agenda today and we also have some impending weather situation, so we're going to be trying to move as efficiently as we can through the agenda, and we will see how much before our estimated end time of four o'clock we can manage, but we have spoken, Hal and I have spoken, and we are going to try to facilitate things as quickly as we can. So with that in mind, let's move on.

DR. SOX: I would like to welcome

everybody to today's meeting of the Executive Committee. I would like to ask you, Sean, can we move ahead faster than the agenda without prejudice to our obligation to the public to have opportunities to comment?

DR. TUNIS: I think we can do that, and I believe the, if there are scheduled speakers other

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than Greg Robb, I'm not aware of them, so as long as Greg is already here, I think we won't be giving any scheduled public speaker any slot.

DR. SOX: Well, we will do our best to end early so that people can get on their way quickly.

We have basically three things to do today. The first is to review and approve two topics from the Medical Surgical Procedures Panel, and Alan Garber, who chairs that panel, will lead that discussion. Then we're going to go over the modifications to the interim guidelines, and I will lead that discussion. And then finally, if there is time, we may spend some time talking about the future role of the Executive Committee in light of legislation that deprived us of the role of actually approving panel reports.

I would like to announce some changes in the leadership of the Diagnostic Imaging Panel. As all of you know, David Eddy resigned from the panel because of the pressures of work. Frank Papatheofanis has taken his place as the chair of that panel, and welcome, and congratulations, and we have been fortunate to recruit Barbara McNeil to take over Frank's position as the vice chair of that panel.

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Barbara is Ridley Watts Professor of Health Care Policy and chair of that department at Harvard Medical School and is a pioneer in the study of diagnostic tests, so we're really delighted, Barbara, that you volunteered to take on this assignment and we're going to work you hard, I can guarantee you. Bob?

DR. BROOK: I just have a procedural question. In relationship to the fact that both the procedures had unanimous votes on them in favor, is it possible that we could just approve the minutes and dispense with discussion on the subject, unless there is something controversial that needs to be brought up that is not contained in the brief minutes we got of both of these procedures?

DR. SOX: Well --

DR. BROOK: Because there was no dissenting vote as I see, on either one of the minutes.

DR. SOX: I think it's a good suggestion, but I think we can achieve the desired compression of our activities today simply by asking Dr. Garber to get to the point, and everybody to try to keep their comments down to a minimum. So thank you for the suggestion, but I think we will follow procedure and

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just ask everybody to pull together. So, anything else before we start? The usual loquacious Dr. Garber. In that case -- yes. Sean has suggested that I give you a brief report on yesterday's meeting of the Medical Devices and Prosthetics Panel.

It was a very successful meeting. We were fortunate to have two experts here just by chance who actually co-edit the Journal of Ambulatory Blood Pressure Monitoring, which was the subject, and they were really very helpful to us. We tried with intermittent success to try to keep the discussion of the evidence separate from a discussion of sort of the broader clinical issues that fall into the category of governed by guidelines and by clinical judgment and clinical common sense, we tried to keep those discussions separate as much as possible, and I think succeeded pretty well.

We had good presentations from the folks who came here courtesy of Spacelabs, which is the company who had made the request for a coverage determination. In the event we endorsed a motion submitted by Ron to -- Ron Davis to, that the, to support the use of ambulatory blood pressure

monitoring in patients with suspected white coat hypertension, this despite some significant holes in

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the evidence, but a sense on the part of the group that there was something there that we needed to endorse.

We considered relatively briefly two other items. One was the use of ambulatory blood pressure monitoring for patients with resistant hypertension and we decided the evidence was insufficient to draw any conclusions, and the same, we drew the same conclusion about the use of ambulatory blood pressure monitoring for evaluating patients who have symptoms of postural hypotension on medication. Any questions?

In that case, let's begin, and I will turn the floor over to Alan Garber to lead the discussion of the med-surg procedures panel.

DR. GARBER: Thank you, Hal. Can you hear me? On October 17th, we considered electrical stimulation as adjunctive therapy for chronic nonhealing wounds. I can summarize by saying we read, we came, we discussed, we approved. The only real discussion in this area, there was a lengthy ECRI report, which you have all received, I believe. The only real discussion was about lumping versus splitting the various indications and the different devices, and the panel concluded that HCFA should

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really make, that the decision about whether the studies applied to all the devices and for all the indications was one that should be a technical decision made by HCFA, and the panel opted to just consider them together as a class, that is devices, as well as the indications.

For some of the indications there was a real paucity of data, but they thought it was not worth splitting them up. So that will be left to be a technical decision to HCFA, and the panel concluded the evidence was effective for this group of treatments as a class, and for the group of diagnoses

as a class.
They felt that the treatment was more effective than alternative treatments. They rejected some suggestions that it be considered to be in one of the categories that was more emphatically positive, and there was just very little disagreement among the panel on any aspect of the discussion. Any questions?
DR. SOX: So you -- I'm looking at the minutes here, Alan, and you have to help me. There's a final panel recommendation about the effectiveness of sacral nerve stimulation, I see, for two indications?

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DR. GARBER: No, no, that's the -- sacral nerve is the second one. We're talking about electrical stimulation for wound healing now. I'm sorry, did I misspeak?
DR. BROOK: No, you did fine.
DR. SOX: Oh, I see. We have two sets of minutes.
DR. BROOK: I move that we approve the first set, if we can do that.
DR. SOX: Wait a minute, Bob. We first have to see if there is any public comment, then we'll have a discussion, and then we will welcome your motion, Bob, thank you. Does anybody wish to comment on the first item, sacral nerve stimulation?
DR. GARBER: No, this is electrical stimulation for wound healing.
DR. SOX: For wound healing, is there anybody here who wishes to comment? Well, there is nobody to comment. Would anybody like to raise a discussion item?
DR. BERGTHOLD: Just very briefly. Did it come up at the panel in what way this is being covered in the private sector by commercial carriers at this time? Did that come up at all?
DR. GARBER: I don't recall that. It's

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possible one of the public speakers might have

mentioned it. I just don't -- Connie, do you remember, Sean?

MS. CONRAD: I'm sorry, I don't.

DR. BERGTHOLD: My memory is that this is covered in a very inconsistent way in the private sector, and that the coverage guidelines in various health plans are quite specific on when they will or will not cover, just to be sure.

DR. TUNIS: Alan, just to clarify a little bit more, is it possible -- it did seem to me that one of the main issues of controversy if any that came up related to the different sorts of wounds, different categories of wounds. And you know, my understanding or recollection taking away was that the panels, the panel's feeling was that most of the evidence upon which they were basing their conclusions was for one type of wound, I believe it was the pressure ulcer, but that the feeling was that one could extrapolate based on that to other types of wounds, but that we didn't get into a dialogue about the issue of do all wounds heal the same or don't all wounds heal the same, and can one sensibly extrapolate from one to another. And I think as you have said, that was sort of then left to be sorted

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out within the HCFA coverage process. But, is there any more detail you can add on that discussion, or just confirm that impression?

DR. GARBER: Sean, I think you stated it very accurately. There were some categories like, I think it was the arterial ulcers, where there was exceedingly little evidence from the literature. And so it came down to, do you believe that different types of wounds heal in different manners, can one extrapolate from one type to another, and the testimony and the literature seem to be completely inconclusive on that point so it was just a judgment call, should you split these apart or should you lump them together. And I believe the judgment of the panel was that in this particular situation, they felt it was okay to lump them together, but they wanted to leave quite a bit of discretion as I

understood the discussion, at the hands of HCFA in interpreting this for specific indications. And it's as Sean said, that the strongest evidence, and I think this reflects the high prevalence, that the strongest evidence was for pressure ulcers.

DR. BROOK: I would just like to put in the record if we're going to have a discussion, that the whole conclusion of this panel is summarized in

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that the evidence is adequate. It doesn't say what kind of evidence, it doesn't say anything -- the ulcers are all included as sort of in parentheses. There is no description of the size of the ulcers, the patients that it refers to, there is no information about how often this procedure should be done, and all those things that will affect billing and reimbursement of course, that are vital to coverage.

I think that at some point down the road we need to discuss this. I have been trying to do this at all the last meetings, about what is a specific recommendation that we come out with here, but I think that in our role of not micromanaging the other committees, I mean, this whole committee meeting is summarized literally in two sentences which will allow you to, or urges coverage of this procedure as many times as anybody wants to do it for any size of an ulcer and for as long as you want to it as long as it is, quote, chronic nonhealing.

And I would also understand that the word chronic is not defined and nonhealing is not defined, let alone wound, but it is the conclusion of the panel.

DR. GARBER: Maybe -- could I just make a

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brief comment on that? I think Bob is largely correct in his characterization, but this was a deliberate judgment of the panel that it would not be appropriate to make it more specific and in all those issues including size, type -- duration actually was not discussed, but the definition of chronic was, and

how old it had to be. All those things were discussed. And the problem is, the literature really uses from study to study widely varying criteria for each of these things, and so the panel felt that there wasn't evidence to make a specific size cutoff for the ulcer or to say X number of weeks or months.

So they were deliberately vague, and I think it is fair to discuss whether they should have been more precise in trying to -- and I would have to say, if the panel had made a more precise recommendation, they would have found exceedingly little literature to address an issue that it should be X millimeters versus Y millimeters for the size of the wound, or three months versus four months, so the judgment of the panel was that it should be broad guidance.

And reimbursement purposes, they thought there were enough technical decisions to be made that HCFA should have latitude in making this more

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precise, it shouldn't be the role of the panel to do so.

DR. SOX: So your point is that in making a recommendation, the panel should take into account the needs of the customer, which in this case is HCFA.

DR. BROOK: I would like to just argue that it's a -- I mean, again, this is a general discussion. These are like criteria that you can't have back surgery unless you have six weeks of back pain in the absence of something going on. This is the form of this kind of a statement. If you're a doctor and you're trying to get coverage for this kind of procedure for an elderly person, you know, and the question is, are we letting it up to HCFA to define what chronic is and nonhealing is, and did somebody try anything else, and all of these other kinds of things.

In criteria, we have to decide generally what we're planning on doing. If you compare this to what we did with PET scanning last time, you could argue that this is analogous to saying that PET

scanning ia approved for anything, because this is much vaguer than some of the recommendations that came out last time about PET scanning. So the level

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of vagueness of the recommendation, or the level of, the number of words or the generalization of these criteria are very different depending on the panel. At some point in the process we are going to need to sort some of that out, Hal.

DR. SOX: I agree.

DR. BROOK: But I don't think it's time to micromanage the committees that work so hard on coming up with these recommendations.

DR. GARBER: Could I just suggest, I think it's entirely appropriate for the Executive Committee to make suggestions to the panel about how specific these recommendations should be, and if we as a body feel these are not sufficiently precise, we should certainly make a public statement to that effect.

I have to say though, that the panel I believe would have been inclined to a great deal more precision, and their judgment reflected the state of the literature, that is, they thought that there wasn't the evidence to support a more precise statement but there was evidence to support the general statement that you see here. And I think that even with different guidelines, our panel was quite adamant that they wanted to lump things together rather than split them, and greater

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precision would not have received support from our panel, but it's entirely appropriate for us to give guidance to suggest greater precision if we think this is not useful.

DR. SOX: Well, it strikes me, Bob's example is a nice example. We were very specific about PET scanning and very general here. And that really, the differences reflect at least to some degree negotiations between HCFA and the panel chair and vice chair about HCFA's needs, which they have some idea about, the specificity that is possible,

given their preliminary look at the evidence. So, it strikes me that in the -- there is no general rule because it will vary as a function of HCFA's needs and the state of the evidence, but that perhaps the panel could be making some suggestions to make sure that those discussions take place at an early stage in the development of the plan for dealing with the problem.

DR. GARBER: Yes, Hal, I think that's right. I would just mention one thing about the history of this. HCFA did pose more specific questions to the panel and the panel, not HCFA or the chair or vice chair, voted to lump together. I'm a little hazy on this, but Connie and Sean can correct

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me if I'm wrong, the panel moved and approved a motion to lump these categories together. It was quite clear this was the sense of the panel. I don't know whether it's what HCFA wanted, but it's certainly not what HCFA and I had agreed to going into the process.

DR. SOX: We might want to keep this issue sort of alive when we get to the discussion of interim guidelines and perhaps make some modest amendments that would reflect this discussion. Yes, Leslie?

DR. FRANCIS: Could I just ask you a question about the procedures? When I looked at the material that was sent to us that I guess was the material the panel got, it was remarkably unorganized.

DR. GARBER: Are you referring to the ECRI report?

DR. FRANCIS: No, I'm referring to the --

DR. GARBER: The background readings?

DR. FRANCIS: The background reading, and I guess my question for you is, did you think that the materials that you received in preparation for the meeting were adequately organized, summarized and presented to the panel in such a way that they could

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do the kind of analysis and discussion that you wanted to be able to do? I'm asking that just for, so we can learn from procedures whether you thought that the processes before the meeting worked or didn't.

DR. GARBER: Leslie, that's a tough one to answer. This is a fairly large heterogenous and not generally high quality literature. The ECRI report and discussion of the ECRI report took a good deal of our time, and that generated a lot of discussion. And I think that basically the panel's conclusions were not the same as those of the authors of the ECRI report based on more or less the same information going in. So in some sense, you could say that the panel did not feel that the evidence as summarized in the ECRI report, which was the main evidence report used for this panel, that they didn't entirely agree with the interpretation that the authors had in mind.

I think that the discussion and the opportunity to ask questions of the principal author of the ECRI report was extremely useful and made up for any deficiencies in the written materials that were distributed.

DR. MAVES: If I could just sort of add to that, I think the materials that we received, and I

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have spoken with Connie and Sean about this, represented kind of a best compromise. I think on a couple of occasions before, I think that we felt that we didn't have AHCPR reports, et cetera, available to us, we didn't have the public comments available ahead of time, and so I think some of the noise if you will in the materials that we received, simply are a reflection of HCFA staff trying to present a more complete package of information to the panelists, and as a result of that you're going to have what seems to be a relatively more disorganized group of materials to review.

But I would agree with our chair, Alan, that I think the quality of the discussion, the deliberations, certainly made its way through all these papers that you see, and I agree with his

conclusions and the conclusions of the panel.

DR. SOX: Sean, do you want to comment on this discussion?

DR. TUNIS: Yeah. It's sort of an interesting issue in terms of the organization and the level of synthesis of the material that gets sent to the panel. You know, we have some constraints on the side of HCFA as, you know, being sensitive about any issue being raised about the extent to which we

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prebias the panel or the Executive Committee in terms of what information we provide, or how we organize it or how we synthesize it for that matter. And you know, my own particular feeling is that, you know, the Executive Committee and the panel are grown-ups and they can figure out if we're trying to, you know, put something over on them, and so our direction is to try to, going to be to try to do, you know, objective summaries, identify the higher priority literature, and still provide everything so that people have the opportunity to go through it. And you know, we may be subject to some criticism of you know, leading the panels on if we go too far in that direction. But I think there is definitely a balance between what you all can possibly digest in a weekend or a week or an airplane flight for that matter, and you know, and what is the full spectrum of information on any particular topic.

DR. GARBER: Could I just add one brief comment? In terms of lessons from the collection of literature for general EC or MCAC operations, this sort of confirmed the beliefs that I've always had that HCFA's effort has to go into making sure that the evidence reports are good, and then being fairly complete in the distribution of literature,

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supporting literature, and that almost never can be well organized outside the context of the evidence report.

And I have to say that although the panel didn't agree with all the conclusions of the authors

of the evidence report, they found the evidence report, I dare say, extremely useful, and so that aspect should not be taken as a criticism of the evidence report. It's better to have one whose conclusions you may disagree with but which is very clear in laying out the evidence, than one that you would agree with but is spotty in that regard. So, I thought the process actually worked quite well.

DR. SOX: The U.S. Preventive Services Task Force provides sort of a reader's guide to the briefing book that helps people to focus on the key articles, the key sections, and to make their best use of limited time, and I think we ought to be striving to point out, what are the key articles that really need to be reviewed, the primary articles upon which recommendations are likely to turn. Tom?

DR. HOLOHAN: I don't know if this will help clarify or not. The VA has the largest system of care for spinal cord injury in the world, and actually initiated some of the original training

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programs in spinal cord injury. Decubitus ulcers are the single most common and most expensive complication. All of the 23 spinal cord centers in the VA are unenthusiastic about the ultimate efficacy of electrical stimulation for healing decubiti but all of them use it, restricting it generally to cases when other more conventional treatment has failed. The specific examples given to me when I called them were patients who have had plastic surgery and the plastic surgeon is unwilling to do a second flank rotation, they will use electrical therapy, and are mildly to moderately pleased with the benefits.

I should also add with respect to Linda's comment, there is no financial incentive in the VA one way or the other to use it or not use it.

DR. SOX: Alan?

DR. GARBER: All right. Tom, I think that is very helpful to know. In interpreting the panel's recommendations was adjunctive therapy to chronic nonhealing, and if you -- we were not given the transcript of the discussion, but chronic nonhealing

meant that it was unresponsive to other conventional therapies, so in fact everything that you said about the VA I think corresponds to the panel's judgment, including the lack of a lot of enthusiasm. The panel

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concluded it was effective, but nobody was overwhelmed with this being a real breakthrough in any sense in the treatment of such wounds.

DR. SOX: Well, I'd like to move this in the direction of a vote. Bob?

DR. BROOK: I would at least suggest that next time, that given this discussion, that the recommendations be amplified, because every time we ask a question, the push back from the chair is that this is what we mean, so I would urge that the recommendation, this kind of a recommendation, it sounds like that three sentences to produce clarity in what we voted for should really be something like three pages in terms of defining the topics, what is meant by it, the intent of the panel, the rationale, almost like a legislature intent when a law is passed. So I would wonder whether our problem is that all of this was discussed and dealt with carefully but that the minutes are just way too brief regarding the summary, so I would urge that at least next time we consider a more detailed set of minutes that includes definitions and these kinds of things in that, around those recommendations.

DR. SOX: Well of course, our interim guidelines, one of our key principles is that the

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panel has to be accountable for the process and the reasoning that it uses in drawing its conclusions, and so far we have not held anybody's hands to the fire. I can feel the ambulatory blood pressure monitoring may be the first example where there will be a report of the reasoning we went through, as well as the motion that we finally passed.

DR. BROOK: And the definitions of what it means. I'm not so much interested in -- the reasoning is not, it doesn't have to be the

reasoning, it just has to be expanding what these terms mean, you know, so that you know, it could be some of the reasoning but it really is -- I'd be even happy if the terms were defined in more detail than what's in the minutes.

DR. GARBER: Well, I'll say mea culpa. I think those are very fair criticisms, and it was the original intent of the Executive Committee to provide for a detailed summary, and I agree in view of the discussion that this is too short.

DR. SOX: Well, I hereby pledge to make the ambulatory blood pressure monitoring report an example.

DR. GARBER: Yeah, do it today while it's fresh, Hal.

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DR. SOX: Right. You know, I just threw away a lot of my notes. I thought I'd seen the last of the problem. Well, in any case, is there any more discussion before we move to a vote? There being no more discussion, I'll ask Connie if she will instruct us in doing the vote so that it sticks.

MS. CONRAD: Thank you. Could we have a motion to ratify or not the Medical Surgical Procedures Panel minutes dealing with electrical stimulation for the treatment of wounds?

DR. HOLOHAN: I move to ratify.

MS. CONRAD: Second please?

DR. MURRAY: Second.

DR. SOX: All in favor? Any opposed? Anybody abstaining? The motion passes unanimously.

We will now go on to a discussion of the second topic.

DR. GARBER: Okay. The second topic was sacral nerve stimulation for the treatment of urinary incontinence. And basically, there were a number of good studies, including one really good randomized controlled clinical trial that in the view of the panel clearly demonstrated effectiveness for both the indications that were on our plate, refractory urinary urge incontinence and refractory urge

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frequency syndrome. And there wasn't very much discussion on this, and the evidence seems to be clear-cut, so the panel said that the evidence was sufficient and they concluded it was more effective than alternative treatments for these two conditions.

DR. SOX: Does anybody in the audience wish to comment, make a presentation? Anybody in the panel have any questions for Alan or any comments about this topic? Bob?

DR. BROOK: Again, it's really interesting to try to read this. The panel noted that neurologic patients had been excluded, but agreed that's an appropriate exclusion. Does that mean that in the recommendation, they ought to also be excluded in terms of defining refractory urinary urge incontinence and refractory urge frequency. And then they say, the panel indicated that refractory incontinence was that precise definition be left to HCFA, yet they voted to support it. It's hard to know what it was that they -- how could they vote to support something if they didn't know what it is, if they can't define it? I mean, that's the way these things read. Now I am sure, again, that this is not the case.

And then Alan just ran through and said

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there was a good study here and the sense of his conversation was that it was better than previously, yet the next sentence says, has not been adequately evaluated, but invited HCFA to take a look at a forthcoming study. So I'm all for -- again, I don't think we need to repeat all of this, I'm all for approving based on the fact that the panel did its job, but I believe these minutes are terribly inadequate and they will lead to, or they could lead to decisions regarding coverage when the nuances of the discussion are long forgotten, and this is the only document that's relied upon that are totally inadequate for HCFA, so --

DR. SOX: Randel?

MS. RICHNER: I think when Hal was saying

earlier that the panels are supposed to provide a written report, that should alleviate your concern. I think right now what you're discussing are the content of the minutes rather than what actually the panel deliberated in whole, and in that written report that should take care of those concerns.

DR. TUNIS: And in the meantime, we don't really you know, use these minutes as the sole product of the meetings. We have the entire full transcript of the meetings and in developing our

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decision memo or coverage memo on this, you know, we go through those minutes in great detail and that's really where we get our direction from, not the --

DR. SOX: You mean the transcript?

DR. TUNIS: The transcript, sorry. So we have access to the entire written transcript and that's really what we rely on, not these minutes.

DR. BROOK: This is a very confusing process then, because we get something that's inadequate that we go through very rapidly, and then you interpret it in some way, in a different way than we may have meant given what's written on paper, that leads to some danger, and I would urge that the process be -- if something could happen -- I know there's time pressures in all this, but if something could happen to make this document good enough that we know what we're voting on, really know what we're voting on, and you think that this contains enough of the message that you could defend what you do based upon this document, I think that's what's crucial, that you should be able to defend what you do based upon this document, because that's why you're convening us, but you can't based on this document, you just said you can't, and that, you know, we know what we're voting on. And the answer to both of

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those questions right now is no.

DR. SOX: Linda?

DR. BERGTHOLD: May I point out that this is -- not only do I not vote, but this is the last

vote that we're going to take, other than the one that was done yesterday. As an executive committee, we're not going to be voting on this anymore.

DR. TUNIS: Actually, no, at least not until October, which is when the new law goes into effect about removing the ratification function, unless something happens before then, which I don't think so, but it's not entirely a moot point, it may be.

And actually, just on that point, and a lot of people have stuff to say, I still think, and we will talk about this later when we talk about the future role of the Executive Committee, that a more content full summary that comes out of the panels that would be looked at by the Executive Committee is still going to be important even when the Executive Committee doesn't formally ratify it.

DR. SOX: So, I don't know who came first, so I'm just going to start closer to me and go farther. Alan?

DR. GARBER: Well, this is sort of a

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question for Sean. I think Bob's comments are valid that there needs to be more detail, and I already mentioned that with regard to the last one that we discussed, but it does occur to me that for some of these question, even a three-page document won't answer all of them, even if these issues were discussed in great detail at the panel meeting. So the question for Sean is whether it would be feasible to distribute the transcripts, maybe electronically so people who didn't want them wouldn't have to print them all out, so that this would be part of the documentation that the Executive Committee has available. It seems to me that the transcript in some sense is at least as valuable as the primary literature that the Executive Committee has received, and many of these questions are clearly covered in the discussion and therefore would be in the transcript. Is that something that we could do in the future?

DR. TUNIS: Connie tells me that actually

the transcripts are posted on the web, so they are available.

DR. GARBER: I think all of these questions then are readily answered by even a quick review of the transcripts, and so it may be good to

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just remind the Executive Committee that they should feel free in preparing for the Executive Committee meeting to read through the transcripts at the time they get the minutes and the report, in case those do not answer the questions that they have.

DR. TUNIS: Just as somewhat of a technical issue, but part of the reason actually that the minutes, there is not as much attention probably as has needed to go into the content, but part of the pressure on those is that our clock for making our coverage decision is linked to when the minutes get signed by the chair of the panel or the chair of MCAC, and so we then have a 60-day time clock from that point of view. So, the longer we take to actually get the minutes done and approved, you know, the longer it takes us to make our ultimate coverage, or potentially, and so part of the pressure has been on that.

But I think what I'm, you know, hearing and we're obviously going to discuss further is you know, that's a piece of the process that we need to think about more carefully, that Bob has raised.

DR. SOX: We will have an opportunity to revisit this several times during this meeting, so I would like to sort of press toward a vote on this.

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Mike? Anybody before we get to Mike? Mike?

DR. MAVES: My only comment is, I think Bob does bring up some important points, and my concern might be, Sean, is from HCFA's standpoint, is that some precision in the language is actually going to be beneficial to you in the long term and certainly as Bob says, when you know, a year or two has gone by and all of us are not in these positions again, and the sort of memory of this has gone by,

certainly could see both on the pro and the con side of this, an enterprising group of people petitioning HCFA, using this language if you will against you, saying listen, this is all you said, you didn't say any more, I have refractory urge urinary incontinence and therefore this treatment ought to be approved. So I think in point of fact, it may actually be helpful for HCFA in sort of limiting those kinds of extraneous exchanges, you know, based upon sort of the record that we have right now. So I would agree with Bob and I think the point he brought up, it might actually be very helpful for the Agency to have more precision in the language of the recommendation that comes out.

DR. SOX: Alan?

DR. GARBER: Just, I want to get back to

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two substantive issues that Bob raised about what the recommendations meant.

The first was the neurological patients and my understanding, we had a neurologist on the panel who was very helpful in this regard, but my understanding is that the neurologic conditions we were discussing are not commonly understood to be part of either urinary urge or urge frequency syndrome, it's a different type of incontinence as usually classified, so that would clearly be excluded from this recommendation, as I understood it.

But the other issue was what do we mean by refractory and there was a discussion about that, and it's very similar to what we were talking about with the wound stimulation. Refractory, the literature used different definitions of refractory and sometimes it wasn't well defined, and so we went round and round on this question of what precise definition can we give to refractory, and this is something maybe we should think about as an executive committee. If the literature is unclear about what refractory is, either it's poorly defined within a study or it varies a great deal across studies, how precise should we attempt to be, because almost certainly if we got very precise, like talking about

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duration and which prior therapies in any detail, we would be going beyond the literature, that was the judgment of the panel in this case, and decided because it was going to be a somewhat arbitrary decision, how you define refractory, that that was a judgment that HCFA should make, rather than a judgment the panel should make.

And here I think the idea is that the panel should be entirely evidence based, and that meant not making a recommendation more precise than they felt they could be based on the literature, but the Executive Committee could easily say no, the panel should make their best judgment, recognizing that the literature is inadequate. But this is just the way the panel came down.

DR. SOX: Something we discussed yesterday in ambulatory blood pressure monitoring was the notion of really two votes; one is a vote strictly on the evidence and then another vote that takes in -- or the scientific evidence, and then another vote that took into account the guidelines, what we heard from experts, our own sort of common sense reading of things, and that's an approach that we may want to think about trying out in other problems. Yes, Bob?

DR. BROOK: I just couldn't follow you,

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Alan, and I'm really sorry about this, but let me just indicate my problems, and again, just put it on the record. Now, when it says that neurological patients were excluded, I didn't read that as the cause of these two problems, but I didn't know whether somebody who had a history of a stroke had been excluded from the primary study, I mean, and what that actually means, in other words, and whether this recommendation would apply. I didn't know whether when you said to the Medicare population, does this apply to both the disabled Medicare population or are we using that as a code word for people over 65 that are on Medicare because they are disabled, and does this deal with people who have

serious, you know, potential disabilities. That's why I'm raising -- this is not a trivial issue -- why I'm raising this.

When you talk about evidence, I really do not know -- I mean, last time we had tour de force of Hal describing that evidence collected in one population may not be generalizable to another population. You just flipped that around and said that if we -- we're going to vote at the highest level, so if there's any difference when we get down to division, the division being the men versus women,

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or other things, and so this flips the analysis around which we did at the last panel, which Hal ran at the panel meeting. It just leads us open to some inconsistencies that we need to solve. Because I don't know what it means that the evidence allows you to draw effectiveness in the Medicare population. To me that means that the evidence both meets internal and external validity criteria, as Hal went through at the last panel meeting. And what you're telling me in your discussion is that's not true, it may meet some broad kind of evidence but it doesn't meet evidence for a specific group of patients with a specific set of comorbidities or conditions. At least that's what I heard you say; I may be wrong about that.

I would like to make one other comment. Please don't -- I mean, it's impossible for us to go through hundreds of pages, whatever it is, of verbal transmissions and get a sense of how that was distilled. I think there is one thing keeping a record for the public on exactly what everybody said to everybody about every issue, but I think it's more important to have a document that's concise, well written, that supports the recommendations at the time that the Executive Committee looks at that

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document, and I don't think this meets that criteria, and that's -- so I would like us not to have to go back through the transcripts but we really do need,

at least in my opinion, a document to do that.

DR. SOX: On that last point, Bob, unless we reverse ourselves during the discussion of the revised interim guidelines, you know, it's in there, and we have to have a process whereby if the chair is too busy, somebody reminds the chair that tough luck, you've got to do it and you've got to do it in time for people to read it before the meeting, we just -- you know, we had a good idea and we haven't followed through on it, and we need to get a system in place so that we do.

DR. GARBER: You know, could I just discuss this thing? I have to admit, I'm not quite sure what Bob was saying about the internal and external validity, but let me just say, the studies were, the vast majority of the patients were conducted in either elderly or disabled people who clearly fit within the Medicare beneficiary population, so that was not really a discussion topic. Usually we're faced with a situation where the studies only in part were conducted in a Medicare population or perhaps not at all. This was a

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nonissue here.

Let me also make one suggestion regarding the transcripts. Notwithstanding the fact that there is a lot of material in the transcripts for both of these issues, the panel deliberations were not that lengthy, and it would not be an undue burden for people to look at the transcripts, and I would strongly suggest that if you have these concerns, look at the transcripts. I'm not saying there is no need for a more detailed report than the minutes, but it would take you a lot less time to look through the panel deliberations and the minutes than almost any of the other materials, and you can see where these issues are discussed. And again, I have to say that even with a three-page or any reasonable length report, it would not contain all the questions that might arise, it would not answer all the questions that might arise, so it's worthwhile and I do not believe unduly burdensome to look through the

transcripts, at least for the part of panel deliberations.

And there is also interesting material in the public commentary but if you want to understand the panel's reasoning and restrict your attention to panel deliberations, you will find that it won't take

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that long.

DR. SOX: Thank you. Is there any more discussion on the topic of nerve stimulation for incontinence before we move to a vote? If there is none, then I will ask for a motion to ratify the med surge panels recommendation.

DR. MURRAY: So move.

DR. FRANCIS: Second.

DR. SOX: Any further discussion before we take a vote? There being none, please raise your hand if you vote to ratify. Anybody opposed? Anybody abstaining?

MS. CONRAD: John Ferguson, I believe.

DR. FERGUSON: I recused myself from voting for the record, because I was a consultant to Medtronic on this issue.

DR. SOX: Thank you. Let the record show that Dr. Ferguson recused himself because of a relationship with one of the manufacturers. Thank you, John. Well, I think that completes the first of our tasks.

THE REPORTER: I don't believe you put the results of the vote on record.

DR. SOX: Oh, thank you. The vote with the exception of the abstention, the vote was

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unanimous. Thank you. Sorry.

Well, the next agenda item is the interim guidelines and just a brief bit of history, we originally formulated guidelines for the function of the panels, and these were published by HCFA I believe in February of last year.

After the first -- we then got comments on those from a number of sources and found ourselves

after using those procedures to have some suggestions about how to improve them, and so the methods working group which I chaired made a listing of all of the comments that we heard and then basically went through them one by one deciding whether we agreed with a change or whether we disagreed with a change. And based on that sort of consensus process, I edited the original interim guidelines to reflect a discussion of the working group. And the changes are all in bold face.

In addition, we incorporated with some relatively small modifications the written guidelines for evaluation of diagnostic tests, which this panel used in its consideration of the various applications of PET scanning, so that -- and that's of course something you have seen before and you have used before. So that's the background, and what I would

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like to suggest is that we just plow through this thing page by page, and if there are changes to me made to discuss them, and in corporate them one by one, and then vote on the entire document, unless we run into a really controversial item, in which case we might take at least a straw vote on the spot.

I remind you that the work group has really spend a fair amount of time on this, and I believe that what we've got here reflects the wishes of the work group, although I did not hear from everybody after sending out the revision that I made. So, some people got back to me with comments and some people didn't, and so it does not necessarily reflect unanimous views of the work group. But the point is, it has taken a lot of work to get to this point and I urge you to take that into account as you make suggestions.

With that as a start, I think we'll just plow through it. Everybody's got a copy? Randel?

MS. RICHNER: Well, I've spent -- I wasn't able to get back with you after your last revision because of work commitments last week. However, in the last two days I have spent a considerable amount of time diagramming the entire guideline from start

to finish, so I have done all that and I have it up

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on a Powerpoint slide, and I think it may facilitate some of the dialog because it actually lays out all of the steps along the way, and I've done it in a broad way and then also in a more detailed way.

So, if you would allow me to have a few minutes to just show you and see if that's useful, I would like to put that up.

DR. SOX: Terrific, do it. So Randel, are you proposing to sort of go through this in its entirety and then we can kind of circle back and grind through it?

MS. RICHNER: Right, exactly (inaudible).

DR. BROOK: Can I ask a procedure question? I mean, everyone has had this document in front of them. Before we spend time looking at this, is it worthwhile to get a sense of whether anyone on the panel has problems with this document?

MS. RICHNER: I do.

DR. BROOK: Besides you. I mean, this has been vetted by -- besides you at this moment, and we'll listen, but the question is, is there anyone else that has problems with any piece of this document?

DR. SOX: I think it's very reasonable to get an over, sort of a sense of where the group is

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with respect to the document before we head into it, if only to allow us to budget time. So maybe what I'll do while Randel is getting set up is just start over with Leslie and work our way forward, and people can just kind of in three or four sentences where you are and if there's some specific area you might want to note it so we can -- but we won't try to solve problems now, we're just getting an overview. Leslie?

DR. FRANCIS: Well, I mean in general I like the structure and content. There are some little questions all the way along the way. Probably the biggest one is the last paragraph before external

validity on page 4, which I just didn't, I thought was internally inconsistent.

DR. SOX: Okay. Bob, what's the big picture here, a three-sentence response? Bob Murray, do you have a comment about just sort of a general take on it?

DR. MURRAY: I'm sorry, too many Bobs on the committee. I found it useful. I did not feel that every word had to be followed slavishly, and found as an overall document, giving guidance to the process, I found it very useful and have no objection.

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DR. SOX: John, your comments.

DR. FERGUSON: No, I think it's a good working document and I think the fact that you added a C on page 5, when the evidence is insufficient, as a kind of a way to look at things as you mentioned with your ambulatory blood pressure, that possibly there was two things, you looked specifically at the studies and then second, all the other sorts of things, and I believe that's very good. And I think, I'm glad that this part was added so there was not a black and white yes or no at the very beginning that would sort of stop discussion.

DR. SOX: Good. Mike?

DR. MAVES: I would agree with those comment, and I would also agree that the section on pages 5 and 6 that goes on is very helpful in terms of capturing some of the information that has been presented by the public or by other independent investigators, and allows us to incorporate that into deliberations. So, I am comfortable with it and am impressed with your efforts.

DR. SOX: Good. Randel, do you want to give your big picture as part of your run-through?

MS. RICHNER: Yes.

DR. SOX: Okay, good. Frank?

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DR. PAPATHEOFANIS: I've been a part of the working group and I have seen the progress made

along the way and I think you have incorporated the comments and suggestions received from a wide variety of folks very effectively. I have no criticism.

DR. SOX: Daisy?

DR. ALFORD-SMITH: I have no concern about the document itself. However, I think there needs to be some consideration in some way given to some of the other aspects that are inherent to this overall process. And inasmuch as we are asked to provide advice on scientific and clinical questions regarding coverage, I think that we also need to at least state our recognition in reference to the accountability that we need to insure not only to HCFA but also to the general public.

And I state that based upon the issue of timeliness as one, which I think is extremely critical. And then the other, based upon the recognition that we are a public entity, that has a need to not only provide advice in this one particular area regarding coverage, but also in an attempt to be responsive to other needs as well.

DR. SOX: Well, I urge you to be thinking about specific language. This is our chance to

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incorporate change and to vote on it. Bob?

DR. BROOK: I pass.

DR. McNEIL: I haven't had a chance to read this since I'm new to the Committee, but I thought it was an extraordinary job and I have a few little parenthetical comments to make here and there, but just coming in from the outside on this, I think it's very difficult to write a document like this, because some people don't want a good document and I think this is a very very good document, and as I said, there are a couple of little parenthetical things that I will talk about when we get to the specific pages.

DR. GARBER: Alan, do you want to say anything? Tom?

DR. HOLOHAN: I think in general it's an excellent document. I thought the earlier versions were good, I think this is better.

DR. SOX: Linda?
DR. BERGTHOLD: I agree. I do want to say something about making the process and the time lines kind of clearer, which is something that I think Randel may be addressing, I don't know, but I had a hard time sort of determining how long this would take and how we would know, you know, whether

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something was proceeding in a timely manner, and also was a little bit concerned, unclear about the different levels of expert review. I got confused towards the end about evidence reports versus peer review versus expert review and what the role of the EC was in terms of choosing expert reviewers vis-a-vis the panel, so if we could clear up that part of the process, that would make it much better for me.
DR. SOX: Joe?
DR. JOHNSON: As far as guidelines and a dynamic document, I have no problems with it. I think that the committee has done an outstanding job on synthesis with the comments and especially with the evidence and the insufficient evidence on page 5, 6 and 7, I like the changes.
DR. SOX: The floor is yours, Randel.
MS. RICHNER: I think I second the opinion of the Committee that the work in progress has been phenomenal and overall I think it's an excellent document, but there are some issues where I think that we could improve it, so that's all I'm suggesting here.
So, the positive from my perspective is that this second bullet in particular is very

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important, to submit non-peer reviewed evidence and policy positions. There are place holders for that in these guidelines, as well as, the public now has a defined place to actually provide input. Okay, it's not moving. There we go.
The negatives, I would say that the timing remains unclear. Is there a portable mike? That the

timings remain unclear, there are too many review steps with no defined process for product of the reviews. And the terminal loop syndrome which, I couldn't think of another way to describe that, where there is a potential for a decision to be reviewed which may cause months or years of delays depending upon how we define it, when there is inadequate evidence. And so, those were some of my primary concerns.

DR. SOX: Randel, I wonder, could we just spend a minute trying to dissect out your comments and make sure we understand them exactly?

MS. RICHNER: Yeah. I'm going to go to the diagram in just a second, and I think that will help a lot.

DR. SOX: Okay.

MS. RICHNER: Okay? So let me just go right to that. All right. So this is the diagram

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broadly of the guidelines, and essentially what happens is HCFA assigns a panel a topic and arranges for a contractor. That means ECRI or whomever you're going to send out for the evidence report. Then there is a production of an evidence report, which is step two. Then there is an external review of the evidence report, and then there is a panel review of the evidence report. Then there is the panel meeting. Then there's the panel report, which is what we were discussing earlier, Bob. And then HCFA receives the panel report. That's broadly what these guidelines say, I believe.

So in dissecting this and going step by step, the first think is, HCFA assigns Panel A, the panel a topic and arranges to contract review. There's no timing. HCFA chooses the contractor to conduct the evidence review of the topic, which happens along the way.

The next thing that happens is the panel chair, and this is in the guidelines, assigns two panel members to work with contractor group as contact experts. That's what we've added, the subcommittee has added this step, which means that

we, the panel members choose content experts to work with the contractor.

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Okay, next step. This is the step that I think is the most important for us, and yet it's the least detailed in the interim guidelines. The key questions are drafted by HCFA, the panel chair and the vice chair, and we all know that those questions that are formed are critical to the success of the ultimate process. So the draft questions are posted on the Internet, which I think is great.

DR. BROOK: So far, you're just informing us what's there.

MS. RICHNER: Right.

DR. BROOK: What I'm interested in knowing is -- but you did make a critical comment about 2.A. You want us to be more specific there, is that your concern? Because up to now, there is nothing about the report that bothers you, if I'm understanding you.

MS. RICHNER: No, that's right.

DR. BROOK: So under 2.A --

MS. RICHNER: Everything is fine up until --

DR. BROOK: Except you want us to be more specific there in the report?

MS. RICHNER: No, I didn't say that.

DR. BROOK: So up through 2.A, we're fine.

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MS. RICHNER: Right.

DR. BROOK: So we're still okay.

MS. RICHNER: We're still cooking, everything is still fine.

DR. BROOK: I just can't under -- we're still cooking.

MS. RICHNER: Where I have a problem, or not a problem but where I think we can improve is on 2.C and 2.Dm and this is written in the guidelines. The draft questions are posted on the Internet, which is great. That allows the public and allows everyone to sort of comment on what questions are being posed.

If you remember correctly when we did PFS, the pelvic floor stimulation, there was a real serious debate about whether the questions were formed correctly for the panel, so this is an important point.

So 2.C is the contractor contact information is provided to the public. This is what we've written in the guideline, so that we know if ECRI is going to be doing the evidence report, we know if Blue Cross is going to be doing it, or whoever the contractor is that HCFA chooses.

The other point is that we have also allowed in our guidelines to have incorporation of public comment at this point, but we haven't defined

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what that means yet either. If a manufacturer, for instance, has clinical data, if a society, a medical society or whomever has additional information that should be part of the evidence report, how is that provided? Is it provided through HCFA or is it provided directly to the contractor. These are just small steps that we can improve in terms of how are w going to get information to the people who are preparing the evidence report.

DR. SOX: So, could we stop here and talk about this?

MS. RICHNER: Sure.

DR. SOX: To see if we want to do this. So one of your proposals if I understand it correctly is that when you post the key questions, you would have the name of some contact person at the contractor; is that correct?

MS. RICHNER: Right. I think that's what we described in the guidelines.

DR. BERGTHOLD: No, actually we discussed this on the phone. I really feel strongly that the comments should come to HCFA and not the contractor. I don't think the contractor should be besieged with industry sort of comments and trying to sift through them. I think that should be organized and funneled

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through HCFA to the contractor that was -- so I'd

like to discuss that.
DR. SOX: Okay, good. So we have an item that we can discuss. So we're going to get a barrage of comments posted, coming by what, e-mail, to somebody. And what do you think is going to happen when all these come in? What's your vision of what will happen, what would HCFA do?
DR. BERGTHOLD: That's a good question. I guess --
DR. BROOK: Well, Linda, I'm just curious. If a contractor has been picked to search through evidence, what's your concern about, as long as the contractor is getting paid to do this?
DR. BERGTHOLD: I guess it's more of a public accountability. I guess it would be how would -- let's say take from a consumer point of view, not an industry point of view, the industry is supplying the contractor with lots of new evidence studies but it's not posted anywhere, it's all going directly to the contractor. I belong let's say to some, you know, consumer advocacy organization, I want to advocate either for or against, I don't have any access to this information. As long as it goes through HCFA, at least gets organized, posted, is

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publicly available, then everyone can see sort of what's going to the contractor.
You know, I have an image of sort of an industry rep calling the contractor --
DR. BROOK: So it's not where it goes, it's that it's posted at the same time that you're concerned about. If we could work out a mechanism where it went to the contractor to be included in their review process as part of the report and at the same time that that happens it's posted on the web, you would be happy with that?
DR. BERGTHOLD: I think so, as long as for example, the contractor's not getting telephone calls from, you know, political representatives or industry people lobbying them to approve or do something one way. If I were ECRI, I would not want to be in a position of getting tons of calls, I would want HCFA

to manage that, so that's my point.
DR. SOX: But on the other hand, if HCFA manages it, that's also a problem from the standpoint of industry who may fear that HCFA will manage it in a way that's disadvantageous to industry. And that's why Bob's suggestion of having two parallel tracks --
DR. HOLOHAN: I don't think Linda really meant to use the word manage.

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DR. BERGTHOLD: No, I meant organize.
DR. BROOK: Collate, collect.
DR. BERGTHOLD: Good.
DR. SOX: Alan.
DR. GARBER: Just a couple of points. First, I think that there is no drawback in having industry directly contact the contractor. The contractor is grown up and they should be able to separate the wheat from the chaff themselves, and I think it could give the wrong appearance if HCFA were indeed managing that process. Although as a contractor, I can see there would be some advantages, I think it's more important to the contractors to have access to all the information.
With regard to publishing the data or making it publicly available, I think this illustrates the danger of us trying to be too detailed about what should be done. Let me describe a common situation. Industry has access to a study that is under review or will be published. This information is clearly relevant to the decision making process and any reasonable contractor would want to have it available. At the same time for reasons of journal publication and possibly proprietary issues, they could not make it publicly

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available at that time.
Now to me, the key feature has to be if this data will always be proprietary and in some sense confidential, it should probably not play a role in our process. But this is a case where it will become publicly available at some point. It's a

disservice to the contractor to not make it available to them. It's a disservice to the process as well, I might add. And yet, that's what would happen if we required posting it. So I know this is not a situation that Linda is likely to have considered, but having been involved in the Blue Cross/Blue Shield process for many years, I know that this comes up reasonably frequently, and we all want to know what those studies show.

MS. RICHNER: We had this discussion in my clinical group about this particular step because of the proprietary information that we provide to the FDA and I said well, perhaps in the coverage process, this will also be an issue, where we want to provide proprietary information. So I think in most circumstances what we would have to do is assume that the information will be publicly available and know that, and would probably be limited not to provide proprietary information to an ECRI or whatever as

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part of this.

DR. GARBER: Right. I think it has to be available to the public at the time that the panel begins its deliberations.

MS. RICHNER: Right, exactly. But it doesn't necessarily have to be public. It can be, you know --

DR. BROOK: It has to.

MS. RICHNER: It does not have to be published information.

DR. BROOK: I believe that if we're taking public testimony from people and everything we do is in the public, we can't even have conversations among ourselves that are not in the public forum --

MS. RICHNER: No, I didn't say public; I said published.

DR. BROOK: Oh, I agree. So, is there a disagreement that -- would everyone agree that we could solve this problem by, the information goes to the contractor but at the same time that the information is sent, gets to the contractor, via a web site or something, that it's posted and the

information is immediately sent to the contractor but it's up on a publicly accessible web site of everyone that's --

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DR. GARBER: No, that's the situation I was describing where it might be available at the panel meets. The contractor begins substantially earlier, so I would just like to amend the earlier proposal to say that it has to be publicly available by the time the panel meets, but I would not impose publicly available at the time the contractor gets it.

MS. RICHNER: Okay, I think that sounds reasonable. And we also discussed that there would be an appendix in the report, the evidence report, that would include all of the information similar to what we received in that massive volume.

DR. BROOK: Can I just -- you're trying to protect something, Alan, and I don't understand what you're trying to protect. Are you trying to protect -- I believe that an industry rep would want to get this stuff out immediately.

DR. GARBER: No.

DR. BROOK: Well, what's the circumstances they wouldn't?

DR. GARBER: Well, some of the best studies are in press or under review at major journals, and it's the embargo policy that prevents them from making them public.

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DR. BROOK: Well, studies, if this is the academic issue of academic publication problem, again, raising its hand and its effect on public policy, we could discuss medical editors at some other time, but the bottom line is that consumers --

DR. SOX: Oh no, we won't.

DR. BROOK: Well, the journal editors as far as I know now have agreed that if you are asked to testify in front of a state legislature where this information is being used for a legitimate public process, that that is not considered prior approval,

I mean that does not result in them pulling the article from the journal. So I would come back and use that statement, that this is a public process, it happens to be an executive one, and if this evidence is going to be included in the contractor's report, it needs to go to consumers at that same time.

If it's not going to be included and just be presented at the last moment at the meeting, so be it. We have a lot of last moment stuff that's included, but my understanding from direct communication with some of the major journal editors is that if this is a legislative process or an executive process, that testimony and this kind of stuff, that that information can be disclosed, and

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even if it's picked up by the press, it will not be considered prior publication.

DR. GARBER: Well, Bob, if it happens to be true that you can post this in its entirety without violating the embargo, I don't have a problem. However, the contractor will need the complete manuscript in virtually every case, and my understanding is that in most of these public settings, it is not nearly as complete as the full manuscript.

If we could get enough of a clear signal from the journal editors that would satisfy the authors of these papers -- it's not just what's reality, it's what their perception is about whether this would affect publication, there's no problem, but I think, I know that authors believe that this would violate the embargo.

DR. BROOK: But that's their right. I believe this is an open public process and our first priority is not to the academic medical journals, it's to the public, and therefore, any evidence that wants to be considered in this process, the public needs to see it at the same time that the contractor is seeing it, and that if people want to do it at a later time, that's their business. But the bottom

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line is, this is a public process, and we all agreed and signed on to this as a public process, so I'm not willing to say that, you know, for three months or four months or six months that are going to -- you know, that the contractor, if they want to look at it fully and include it in the evidence report, I believe it needs to be available to the consumers.

DR. GARBER: Well, Bob, I guess I really disagree. I think this is a public process and it's important to preserve the public process, and I don't think we should have the contractors shoot themselves in the foot in order to make this data publicly available somewhat earlier. If this in any way diminishes the amount of information the contractors have available in order to carry out their responsibilities, we will harm this process, we will not be providing a benefit to the public if nobody gets this information until the articles are actually published in the journals.

DR. SOX: Wouldn't it be reasonable to -- I mean, I think I'm hearing Bob say that when you send a manuscript to the contractor, effectively you should post it on the web site so it's publicly available in full. And I guess you'd have to ask yourself, what is really the purpose of doing that

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and certainly one the purposes of doing that is to make sure that people whose interests are at stake don't get surprised at the last minute when you actually get into a forum where we end up with a vote that could be adverse to their interest. And so, if that's a correct statement of the purpose of public availability, then having the evidence report on the web site ten days or so before a panel meeting seems to me to give adequate notice so that people don't come in surprised and get to an unfair advantage.

Let's see, we're -- so, I guess I'm proposing that for manuscripts that are unpublished, that they need not be published on the web in advance of the meeting. As Alan said, that may deprive us of important information that could be prejudicial to somebody's interest.

MS. RICHNER: There's probably a compromise to this in some respects. If it's a publication of clinical trial results for instance, there may be a way to work with the manufacturer and the authors to provide the data without the interpretative results of a publication perhaps. I don't know. I mean, there may be some other alternatives.

DR. SOX: Okay. Now we're going to stay

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with this issue and we'll just start with Leslie, who has been waiting a long time to comment, and see if we can't get to consensus.

DR. FRANCIS: Well, I actually wanted to raise another issue about stuff getting into the picture.

DR. SOX: Let's stay with this one first.

DR. FRANCIS: We'll finish this one first.

DR. SOX: John.

DR. FERGUSON: This has been an old issue at the consensus program at the NIH, whether authors giving information on a public forum that hadn't been published yet, and I think it needs to be handled on a case by case basis. There were very few times that an author refused to make something in paper available that they presented to the body because they were afraid of publication, and most of the time charts and basic data could be given to the contractor or however you want to manage that, but I think that most of the time that data can be useful, and obviously it hasn't been interpreted as you say, it hasn't gone through a final revision for a publication paper, so I think that this can be done, and there's an old history of it at the NIH in their consensus program.

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And the second thing I would like to say is that I would like Randel's diagram, I hope to be available to the panel, because it's a very nice way to discuss all these things.

MS. RICHNER: Thank you. It was a lot of

work.

DR. SOX: Okay. Other comments?

DR. McNEIL: Actually, I agree with Alan's position on this. I think if we were to withhold data from the contractor because investigators perceived that their article might not be published, or worse still, if they thought that it could be copied, that in many situations, it's pretty easy to quickly ramp up and do a copycat study, I think that there is a real issue of not getting data to the contractor. So I think your proposal of putting it on the web or some place ten days before, whenever, is fine, but I don't think it needs to be published at the time the contractor gets the information. I think that will do a disfavor.

DR. SOX: Okay. So I'm just going to summarize what I think are the key points here and we'll see if we can get to consensus. People who want to have information that's unpublished be incorporated or considered for incorporation into the

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evidence report will send that information to the contractor and send it to HCFA. HCFA will publish it on the web with the exception of manuscripts that are under review or in press. However, we do expect authors of such manuscripts to make the full manuscript available to the contractor so they have all the information necessary to draw a judgment about the relevance of the research report to the evidence report.

DR. BROOK: Can I ask a question, Hal?

DR. SOX: Wait a minute, let me finish.

DR. BROOK: Let me just understand, how does this work? Let's say I've done the only randomized trial of the stuff that's coming in front of this committee. All the relative literature is ridiculous compared to this one trial, funded by a manufacturer, in peer review, and it's part of the contractor's report, and he says all the other evidence is meaningless. Comes to the panel meeting and it still hasn't got rejected from JAMA, and now what? And we're trying to -- they're trying to make

a discussion.
DR. RICHNER: I like John's idea of case by case.
DR. BROOK: I'm giving a case.

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DR. SOX: Well, I think he's right, Bob. I think this is an issue that needs to be taken up with the panel chair and with the chair of the Executive Committee, and work through it on a case by case basis and the best that we can we do is lay out some general guidelines. And what I'd like to do, because I really want to --
DR. BROOK: I want to know what our general guidelines are going to be. Let's say the panel chair says that's right, we're going to -- we can't share the full manuscript with you, I've seen it, two people have seen it, based on this, we're going to approve this.
DR. SOX: Yes, Alan?
DR. GARBER: I agree it needs to be done on a case by case basis, but let me say what approach I believe we should take in the case that Bob raises, and that is, at the time the contractor begins the report, we get a commitment from the authors, because the panel dates are set well in advance, that it can be made public at the time. If the answer is no, or it's got a lot of contingencies that we cannot necessarily guarantee will be met, then it will not be considered, and HCFA might decide well, we will defer consideration of this issue, or they might

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decide to go ahead. But it's very simple. We get a commitment that it can be released publicly, say ten days ahead of the panel meeting and if they say no, then the contractor may choose not to consider that information.
MS. RICHNER: That seems reasonable to me.
DR. SOX: May or shouldn't? I mean, if it can't be available for discussion at the public forum, it should not be incorporated into the evidence report, seems to me.

DR. GARBER: Yeah, that's probably right.
MS. RICHNER: Another issue here. There were very few timing outlines, but this was one of the time lines. It said posted for only one week and I don't think that's actually, I have to say, I don't think that's enough time right there. I think we need a little more time for, you know, once the questions are posted and the contractor information is available, getting information to the contractor should be longer than a one-week time frame.
DR. BROOK: Could I just go back to this? Linda, are you okay with your consumers not getting this information until ten days -- that the contractor has this information earlier than the consumers?

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DR. BERGTHOLD: I'm feeling uncomfortable about it. I don't know. I'm trying to think about what other kinds of things, I mean, it takes consumer organizations a lot longer sometimes to mobilize and react. I would actually like to have some reaction about that. If the industry knows about this and the contractor knows about this, but the so-called public doesn't know about this until ten days, I am uncomfortable about that, but I don't know what to do about it other than it would be, it would go to HCFA and something would be posted as to what was being sent to the contractor so that people could ask for that information.
I also would just like to ask the group to react to, are there other kinds of information and lobbying activities, for example, quasi-clinical, quasi-political lobbying that might go on to a contractor during this proses? I don't know, you know, for example -- I guess Wade is gone.
DR. SOX: Linda, I'm going to ask you to hold that idea, because I want to get through this business of dealing with unpublished manuscripts and get the yes on that, if possible.
DR. BERGTHOLD: Okay. That may be Leslie's other issue too. Okay.

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DR. SOX: So basically you're saying you're uncomfortable with consumer groups having a relatively limited time to mobilize, but that maybe -- in a way it's the issue of competing public good, is it more important to have access to a potentially important manuscript to shape the evidence report, but that may come at the expense of some mobilization time, for public good, so I think we have to form a judgment about that.

DR. BERGTHOLD: It gives a huge advantage to industry, which has an advantage already. They have advantage in terms of money and lobbying organizations and so forth. They will know about these reports presumably, before --

MS. RICHNER: (Inaudible) advantage or disadvantage. I mean, what we're talking about essentially is whether or not there's going to be clinical data to support a technology available at the time of a report. Now the possibility would be that we, you know, if we have a consumer group such as a female incontinence society, would be very interested in having that technology supported, that perhaps they would ask for a wait to delay the report until the evidence is available publicly. I mean, there's other alternatives to this.

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DR. BERGTHOLD: Just clear one thing up for me. If a certain company does a research study and it's proprietary, or it's about to be released, and they share that with the contractor. That means they don't share it with other industry reps, they just share it with the contractor, is that right? So the only people who would have access to that would be the contractor and the people that did the study, right?

DR. SOX: Right.

DR. BERGTHOLD: We're not talking about --

MS. RICHNER: We've already gone through an FDA process too, and we have to know, you know, before we'd be coming to the coverage group, we've already been approved by the FDA.

DR. HOLOHAN: Yeah, but that doesn't mean the FDA approval was based on evidence, we all know that. Most devices are 5-10Ks.
MS. RICHNER: That's right.
DR. HOLOHAN: Okay. So there's no evidence.
MS. RICHNER: I wouldn't say a blanket statement such as that.
DR. HOLOHAN: Well, I will.
DR. SOX: Okay, Leslie, you have been

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waiting.
DR. FRANCIS: Just a couple points about consumer groups. I mean, they may agree that they would like to support the technology but they might not, and so to the extent to which consumer groups are going to want to say a variety of different kinds of things, it could be problematic not to have them have access to it. The other thing that has been worrying me, and it's partly relevant here but it's also relevant to the other kinds of issues that I think Linda is raising, is that consumer groups may have a special concern about particular types of patients and access to a technology.
For example, they may have concerns about local carriers turning down any request for coverage when a patient has Alzheimer's disease. I gather that happens on a pretty regular basis with respect to some kinds of requests for coverage. And so, one of the things they might want to be able to do is get questions posed that deal with that kind of question, looking at whether or not it's a good idea to include or exclude certain groups of patients, you know, addressing that in some way, and that may be relevant to looking at clinical studies to see whether they controlled for that condition or whether they

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addressed that kind of issue. It's also relevant later to how we might want to get public comment in there.
DR. SOX: Responses to what Leslie said,

anybody want to respond to that?

DR. BROOK: Yeah. The only articles we are talking about that fall into this category of response would be that the article has been accepted, revision has been accepted, and a publication date has been set. Any author will not -- so this is not articles under review or have been completed, or are being revised, because under all of those conditions, you can't control the medical editors. So the only article that this affects, now, you will know the publication date when you have to sign this agreement with the contractor if you believe that this is going to be pulled.

And all this is is the question of where in that process, is it at the same time, is it ten days, is it a month before, that we agree to do this? And I agree, they may or may not want to support the technology. The question here is, do we want to leave it up to the panel chair and say that it has to be by the date, at least ten days before the meeting, but it still doesn't have the data. Now it really

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would be useful if the government really -- the industry funding some of this technology stuff is, and it would really be nice if the government took on the medical editors and said, for a public process like this to decide coverage, that it expects all the people that have grants or contracts to comply and submit information, and not wait for a year and a half until it's published. And that's what I'm worried about, or it's under review.

The timing between completion of a manuscript and publication could be two years, it could be two years. And we're only talking about 10 percent of this, because we're talking about the group of stuff that already has a publication date, Hal. I mean if you really think about this, it has nothing to do with manuscripts under review and it has nothing to do with manuscripts that say please revise, and nothing to do with manuscripts that the publication date is set after the panel meeting, which is very characteristic, so it would only have

to do with one or two key manuscripts.
DR. SOX: Okay. Let's continue the discussion. Do you want to respond to Leslie's point?
DR. GARBER: Yeah. I think Leslie's, I'm

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not sure if it was her second point or an elaboration of the first, but with regard to the consumer group about specific groups of patients, that really comes down to input into framing of the questions rather than the types of data, and absolutely that needs to be done, and that's a different part of the report really, but it's about -- well, no, it's not, it's right here, the key questions 2.A and 2.B, so that's important, and I think it bears underscoring the effort that we should make to insure that they have input to the framing of the questions.
But a part of Leslie's question I think was addressing Linda's point that the consumer groups should get this information as early as possible and I agree with that.
Now let me just remind everyone that these I think remain interim guidelines and we have two paths that we're really discussing. One is to only consider data that can be publicly posted at the time the contractor gets it. The other option under discussion is only data that can be publicly posted when the evidence report is posted.
And the question we face, and Hal has phrased this as two competing public goods, and my suggestion is that first of all, if we find out we

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have problems with whatever choice we make, we should change the rules at that point. So if we find out that consumer groups feel that they are ill served by this process, if we go with the option of posting at the time of the evidence report, we should revisit it and we should certainly change it. I am urging that we go with posting at the time that the evidence report is posted, because my sense is consumer groups, despite the concerns both you an Linda have

raised, will not find that this process does them a disservice. But if they do and we go this route, we should change it.

DR. SOX: I'm eager to vote on this and I'm going to ask Alan while we're continuing this discussion to try to jot down notes so he can make a proposal that kind of incorporates everything. I think we're really getting pretty close here and this has really been very valuable.

DR. BERGTHOLD: Can I ask one more clarifying question about this?

DR. SOX: Well, we're not ready to vote yet.

DR. BERGTHOLD: Oh, okay.

DR. SOX: So, I want to take people in turn. John.

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DR. FERGUSON: Just a question to HCFA. When do you announce that a meeting is going to take place, a panel meeting on an issue? Is this several months? You have to put it in the Federal Register, I think, and when do you put it on the Internet, because that's when all the various consumer groups and everybody else that wants to have input might contact you.

MS. CONRAD: John, we set a date, we find a place to hold the meetings, and contact the panel members. They are our first priority. Then we publish a Federal Register and put it, we publish the Federal Register notice and we post our intent on the web site at the same time.

DR. FERGUSON: And that's generally what, two to six months before a meeting, or what are we talking about?

MS. CONRAD: We try to do it at least ten weeks before a meeting.

DR. FERGUSON: Thank you.

DR. SOX: Other comments? Linda.

DR. BERGTHOLD: Let me just ask a question. When we talk about evidence going to the contractors or information going to the contractors, is there any requirement, do we have any requirement

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that all information going to the contractor gets disclosed? What I was also talking about, not just published studies, but what if a senator or representative decides to call, or have somebody call the contractor to tell them that they are particularly interested, that they find that evidence is good, which is something that has actually happened occasionally from time to time, more than occasionally. Does that get disclosed in this sort of -- where does that get disclosed, in the evidence report that the contractor prepares, I received a call from --

DR. GARBER: In the Washington Post.

DR. TUNIS: I mean, from a practical point of view, we don't post on the web every piece of paper we get on a topic. As far as what we are -- however, everything that we get is obtainable through the Freedom of Information Act and basically if anybody asks for something that we would release under FOIA, we'll give it to them immediately as opposed to having --

DR. BERGTHOLD: I'm not about you so much.

DR. TUNIS: But letters from senators, et cetera, we don't tend to post, it doesn't mean they're not publicly available, you just have to ask

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for them.

DR. HOLOHAN: But you have to know they exist before you can ask.

DR. TUNIS: Yeah, but you know, you can make some good guesses about things that exist, but anyway, yes, that's true.

DR. BERGTHOLD: That was one of my points about sort of funneling things, I didn't mean to say managing, but funneling things through HCFA is there is public accountability at HCFA, you could get it. Now we're saying that anyone could contact ECRI or Blue Cross TEC, or the evidence practice centers and tell them what they think about this study as long as they know that's the entity doing the review. And we

won't know, we being the public, won't have any idea that there are these letters, these phone calls, and is there anyplace where the evidence -- what did we call this -- the evidence contractor has to disclose who they have been contacted by? They don't have to, do they?

DR. TUNIS: No, the contractor has been -- I mean in the past the contractors have not tended to have been contacted by the interest groups to a great extent, and certainly not provided anything other than --

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DR. BERGTHOLD: I know, but now we are basically opening them up to lots of contact, right? We're telling the whole world that ECRI is doing this evidence report and we're telling everybody, you can call ECRI and tell them what you think.

MS. RICHNER: Alan, from your experience being on Blue Cross, I mean certainly this is an established process for many years. I mean, one thing Blue Cross does is that they have an open hearing when they're preparing the reports and provide an opportunity for people just like this to come and provide lots of information to them. I mean, you have to put this in perspective. I mean, I don't know if this is going to be as severe as you think, but I don't know.

DR. SOX: Alan, do you want to respond to Linda's point?

DR. GARBER: Yeah. I mean, there is a big difference between this and the Blue Cross/Blue Shield process in that the Blue Cross/Blue Shield process is not open, it's not public, and there doesn't ever need to be any public disclosure on the terms of the process.

By my concern about -- I think Linda's concerns may be valid since this has political

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aspects in the process, but there are so many contacts that are of the nature where the contractor wants some technical information about study design

and so on, where I don't think any reasonable person would say the issue was influence, it's just getting some facts out there. And I'm afraid that if you impose too many requirements in the way of making this public, you're going to interfere with that process, so there's this balance that needs to be struck.

I don't have any great solution, but in terms of a record for initial contact, we could ask that all initial contacts with the contractor be by e-mail so that there is public documentation with a copy to somebody at HCFA, but I would not be so restrictive about subsequent contacts with people who have already been identified by that means, simply because I am afraid that might deter the information transmission process. I haven't thought about this much and I don't know whether that's the right solution. I understand the need to have some record of at least which groups contacted them, but I'm afraid anything more extensive than that would be too cumbersome.

DR. BERGTHOLD: Then that's okay.

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DR. SOX: My sense is that you know, these are interim guidelines, they're always going to be interim and always changeable if we run into trouble and we make our best guess, and then change later.

Alan, I'd like you to, if you could, just summarize the essence of the proposal here so we could take a straw vote and move on.

DR. GARBER: Well, I will give my version and I hope this reflects the sense of the Executive Committee, that contractor information should be released to the public at the time that the evidence report is released to the public, and this is something about which we haven't had much discussion, and that evidence that cannot be released to the public at the time the evidence report is posted may not be considered. Does that reflect the sense of the Executive Committee?

DR. SOX: Yeah. And in a way, all the other things we talked about, about editors and so

forth are kind of --
DR. GARBER: Subsumed.
DR. SOX: -- details, but that's the essential principle, and probably dealing with principles rather than details will serve us well.
DR. TUNIS: Can I ask a clarifying

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question in terms of -- a key issue here is that the reason for not releasing some information to the public would be because it was proprietary information that's prepublication, or is the issue around that the information is proprietary and it wouldn't want to be released, or is it about the potential impact on publication?
DR. GARBER: I think it could be either and I don't think that we want to get into that, because for our purposes, this is a public process and has to be publicly available at some point.
DR. TUNIS: Yeah. Well, the only reason I raise it is that in the, in this new benefits improvement act, that has some statutory language on release of information and proprietary data is specifically excluded from needing to be released. And so it actually, even though -- it says, the language is, all the information used to make these coverage recommendations, coverage decisions, must be made available -- make available to the public the data other than proprietary data considered in making the determination. So there's actually a statutory protection against the requirement.
Now you as an Executive Committee can obviously decide you won't consider --

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DR. GARBER: Let me just say how I personally would respond to that, and that is that if it were to remain proprietary, I think we have lost nothing by excluding it from the process. Let me add, that's based in part on Blue Cross/Blue Shield process, which does -- it looks at proprietary information, and I can't think off hand, and Barbara might correct me on this, but I can't offhand think

of a single example where proprietary information itself would have swayed the decision ever, because virtually all compelling studies get published.

DR. TUNIS: I just wanted to make it clear that an issue here is not that we would be legally required to release it, that's not an issue, but you could still decide that you would not choose to consider it.

DR. GARBER: Right, and I think that we would want the language to be consistent with the legislation.

DR. SOX: Again, we're going to take a straw vote on the principle that Bob has, or that John, that Alan has suggested, and all the discussion ought to focus on that, and we can do it. Bob?

DR. BROOK: Just to make sure we know what we're doing, the vast amount of unpublished data that

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we will get under this rule of protecting the medical editors is stuff that's favorable to the technology, because the only group that will push the investigators to release that data under any circumstance that may compromise the ability of the authors to get their ego massage and published in peer review journals of higher quality because of the editors will be those that the industry supports, and those would be ones that would be positive. The industry is not going to push for somebody, they're going to hide behind this banner and say look, you don't have to release the data when the study is negative, so the studies that we're going to get, the unpublished studies will be biased, even though they may be important, they will be biased toward showing efficacy and effectiveness. We need to know that unless we can figure out a way of balancing this out, and I would just urge that when the committee, when the contractor looks at unpublished data, they know that given this rule and how we're tackling it, that that's what's going to occur.

There is no incentive to have a -- you know, if you're working with the New England Journal on a negative study, there's no incentive to share it

with anybody, because it compromises your ability to

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get it published, and there's nobody that's going to pressure you to share it with this committee. And that really bothers me, especially when a large number of the negative studies may actually be funded by government money that will affect the other part of government making millions of dollars and maybe even a billion dollars worth of decisions about coverage, and that's sad.

DR. SOX: Mike?

DR. BROOK: All because of the tyranny of the medical editors.

DR. MAVES: I actually like Alan's language and support that, and in fact I was a little concerned about this, and I think I join with Bob in some concerns. One of them was what the role of the peer review process would be of the journal but as both Bob and Alan have indicated, these would only be papers that have a set publication date, so that part of the peer review process has come about. I think releasing these to the public affords the second peer review which we've all seen, and that is the commentary by other individuals in the science or from lay people to comment on that.

The only concern I have, I'm sure we've all seen this and I have been party to some of these,

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where we design what we think is the seminal study and we're certain that it's going to be the key piece of information. That may or may not occur, but I think that's going to be a decision that's going to have to be left to that panel and eventually to the Executive Committee, if we are given that right to do that later on.

So, I actually think it's a reasonable compromise. I understand Bob's concern that you're only going to get positive studies on this, but it also I think serves as a check for not putting in information that's not at least been through the first part of the peer review process.

DR. SOX: Any other comments before we vote?
DR. BERGTHOLD: I just need to clarify. How can you incorporate public comment at 2.B if you don't post the information until 2.F?
MS. RICHNER: No, no. 2.B is drafting the question that is going to be posed to the contractor.
DR. BERGTHOLD: But the contractor contact information -- oh, I see. You just tell who the contractor is going to be?
MS. RICHNER: Right.
DR. BERGTHOLD: And then between 2.B and

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2.F, the contractor does the evidence report.
MS. RICHNER: Exactly. This is the detail of our interim guidelines.
DR. BERGTHOLD: And not until 2.F then, does the general public know what it was that the contractor looked at?
MS. RICHNER: No, because if the questions are posed properly --
DR. BERGTHOLD: The questions are posed, but not the kinds of studies or the kinds of contacts or information.
MS. RICHNER: Right. I mean, this is something that we should probably think about in terms of if we want to develop this a little more.
DR. BERGTHOLD: I think we should just -- I'll leave this now, but I would -- Leslie may have a better idea, but I would at least like this flagged as something we would, as we go through this process, we want to look at, to see whether or not it really works out the way we hope it will.
DR. FRANCIS: Presumably what's happening between 2.B and 2.F is in part that the contractor is out there looking for the information. It's not like the contractor gets this bolus of information at 2.B, so you couldn't post all the studies. I mean, part

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of what you hire the contractor to do is to look for the studies. But, the issue that I think is

important here is to be sure that they get the studies, and that -- well, first that they've got the questions framed in the way we want to have the questions framed which, you know, you may have one take on it, I may have some other takes, you know, we all have different takes on that, and also though, that there is enough time for people to be sure the questions are framed right or that more questions could get framed if need be, and to understand what information would be helpful to try to make sure that the evidence folks get.

MS. RICHNER: That's actually a very important point, because in terms of once those draft questions are posted on the net, who then decides whether or not those questions need to be modified, will it be the panel chair, will it go back to the panel chair after they get public comment on how the questions were posed? Who decides that they may need to be changed?

DR. SOX: Well, the same people who are responsible for formulating them in the first place, which is --

MS. RICHNER: Which would be the panel

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chair and vice chair.

DR. SOX: And the evidence report contractor.

MS. RICHNER: Okay. That's not delineated, and so I'm thinking perhaps there should be some kind of process delineated for that.

DR. SOX: Let's vote on Alan's principles before we start spinning off into other orbits. Anybody else want to make a comment on Alan's principles before we vote? All in favor of his principles, raise your hand. This is a straw vote, even I can vote on this. Anybody opposed? Anybody abstaining?

DR. ALFORD-SMITH: I'm just confused.

DR. SOX: Would you like a restatement?

DR. ALFORD-SMITH: Please.

DR. SOX: Please, Alan, a restatement for Daisy.

DR. GARBER: That contractor information is released to the public at the time that the evidence report is released to the public, and I forgot my wording on the other part.
DR. SOX: That was the best part.
MS. RICHNER: And information that cannot be released cannot be considered.

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DR. GARBER: Oh, yes. And information that cannot be released to the public at the time that the evidence report is released to the public cannot be considered.
DR. SOX: By the contractor.
DR. ALFORD-SMITH: So that's what we voted on?
DR. SOX: Yes. Would you like to vote?
DR. ALFORD-SMITH: I'm in favor.
DR. SOX: Okay. So we have decided that now, a really important discussion that took us some good places. So now we need to move on, and -- yes, Barbara.
DR. McNEIL: Could I just ask something for clarification, Hal? I could imagine we could be here until Sunday going through, so the question I have for you is, are these going to be interim recommendations or are these final recommendations at the end of this whole process? What is the process by which these get fine tuned after we put these out?
DR. SOX: Same process.
DR. McNEIL: So we don't have to feel compelled to solve every single problem today?
DR. SOX: No. It's going to be a rolling process. We will probably revise them yearly until

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we get to some point --
DR. McNEIL: I have the feeling -- the reason I ask this, I have the feeling that some of the issues that we may raise today are going to become much clearer as we move along, and to try to force feed answers right now is going to do us a disservice.

DR. SOX: I think a number of people have said what Barbara is saying, let's lay it out the best we can and try it out and if it doesn't work, then we're going to have to change it, we should, so that's a good reminder as we try to move forward. But again, I think this was, it took us an hour to work through this, we ought to try to go faster next time, but it was a very important discussion, and thank you, Bob, for getting us onto it.

DR. FERGUSON: Hal, question, just one question. Am I to understand correctly that the public announcement that this meeting is going to take place occurs before this slide; is that correct? In other words, at the time you announce there is going to be this issue tackled by MCAC in the Federal Register and on the web, that no contractor has been asked already; is that correct?

MS. CONRAD: That's correct.

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MS. RICHNER: That can't be right, Connie, because the reason is that what we are talking about is preparation of the evidence report, which could take months and months and months.

DR. FERGUSON: So that means that HCFA contacts the contractor months and months before announcing that the meeting is going to take place?

DR. TUNIS: Well, I think there is, again, there's many pieces to this process and it's even changing because the role of the EC is changing as well. Typically we have decided to send something for a TEC assessment long before either the EC, anyone on the MCAC knows that we're even addressing the issue. So what we're potentially proposing here, I think it sounds like it's on the table, is that the Executive Committee might be getting involved much earlier in this process to give us some guidance, you know, earlier on before we even commission an assessment report on this aspect of setting up the assessment report, if I'm understanding this correctly. But generally in the past, MCAC hasn't been involved in this part of the process at all.

DR. SOX: Which part?

DR. TUNIS: The part of scoping out the questions for the evidence report, you know, the

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Executive Committee or the MCAC doesn't even, wouldn't even have knowledge that a particular topic has come in, been accepted for a coverage decision until we are much further along and even close to having a draft of an evidence report.

DR. SOX: But the panel chair will be involved, will he or she not?

MS. RICHNER: This is what we have written in our interim guidelines and we're presuming that we are part of perhaps a new technology assessment for the panels, which is separate from what you have already triggered at HCFA.

DR. SOX: We have written something that makes a lot of sense, but we haven't implemented it at all yet, and I think in the matter of getting the panel chair and vice chair involved in formulating the key questions and the analytic framework, that's really important, because otherwise, the evidence report may be looking in this direction when this is the right direction to be looking at.

DR. TUNIS: Yeah. I mean, if you think about the ambulatory blood pressure monitoring report we had yesterday, which was quite a useful report, but you as the panel chair had no involvement, you had never seen that report until you got it

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finalized, I assume, in the package with everybody else.

DR. SOX: I saw it a little earlier.

DR. TUNIS: But I mean, you weren't involved obviously in the early part of the process before that.

DR. SOX: Well, the thing is, we formulated the key questions and the analytic framework well after the evidence report had been written, but in time to organize the meeting around those key questions.

Okay. So, let's go on, Randel.

MS. RICHNER: I've got more here. What we had first was the step about preparation of the evidence report. Now we get into the whole thing about the review, and the review -- actually what I'm going to do --

DR. FRANCIS: Before you go on, can I -- there was that other question about, that Linda and I were raising, about input into the formulation of the questions from consumer groups who take a while to get organized, and I just want to be sure that there is -- that we don't have something that's so formalized and sort of written in stone so that we can't have a way to get more dialogue about the right

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questions, and the way you're framing it, it got -- you know, I mean often what will happen is that a request for national coverage, as I understand it, requests for a national coverage decision may well come in from industry, right?

MS. RICHNER: Or a position group.

DR. FRANCIS: Yeah. It's likely to come in from -- now, consumer groups might do it, but it's likely to come in from somebody who has an organized economic interest.

MS. RICHNER: Well, you know, medical societies are --

DR. FRANCIS: Yeah, sometimes, okay.

MS. RICHNER: (Inaudible.)

DR. FRANCIS: No, that's true. But I just want to be sure on that other side that we're, we have a way to get at the questions that are affecting how people actually get care.

DR. SOX: The process that we've outlined and that we are going to some day ad here to is that before the evidence report even gets started, we formulate the key questions, we post them on the web, we get time for public comment, we modify them as needed, repost them, and then start the evidence report to focus on these key questions. That's the

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process.

DR. FRANCIS: Right. And we might want to have just a kind of continuing invitation to groups that might want to be sure that questions -- some sort of continuing opportunity for dialogue on questions while the evidence process is going on. I mean, it may not be possible to get them fed into the evidence report, but it might be still be helpful to the panel in its deliberations.

DR. SOX: Okay. Randel, tell us where you're taking us, because I think everybody is kind of worried that it's going to be six o'clock and the snow is going to be 12 inches deep.

MS. RICHNER: I'm sorry, but the other big chunk of our interim guidelines is the review process of the evidence reports.

DR. SOX: That's next.

MS. RICHNER: And this is next. And what I've tried to do is summarize where we have written in the interim guidelines, there's actually four different reviews of the evidence report, so this slide sort of summarizes that. What we've built in, Hal, are MCAC, we've suggested that there should be the MCAC panel nominates two primary reviewers from the panel to review the evidence report. Then we've

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also said that there will be three, two to three external reviewers, that's in another part of our interim guidelines. And then there is the MCAC panel member review of the evidence report, and then there's the public comment on the evidence report. So we actually have four different mechanisms we've written in the interim guidelines of review of the evidence report.

And the issue is, how is that going to be essentially consolidated, and it's a concern because if you look, this is what we've written in the external review of the evidence report. We've detailed five different steps and it's rather confusing. And so, that's why I wanted to make sure that we were all clear about what we have mandated in the guidelines for the review process, because I'm not sure how we're going to then consolidate those

reviews, especially if we get a negative --
DR. SOX: Let's go back to the slide you just showed earlier where you raised that question and we can talk about it. So, why don't I tell you what I think?
MS. RICHNER: Okay.
DR. SOX: The external reviewers prepare a written report that's made available to the public

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and to the panel 10 days or whatever the timing is before the panel meets. So it's part of what they read in preparation for the meeting.
MS. RICHNER: And those are nominated by the Executive Committee, that's what it says in the guidelines, the Executive Committee nominates two to three external reviewers.
DR. GARBER: Where does it say this?
MS. RICHNER: Unfortunately, I have all of my page numbers associated with all of these, and I left them in my hotel room.
DR. SOX: It's actually the chair, and I will read it. HCFA should provide a list of potential reviewers from which the panel chair and vice chair can form a slate.
MS. RICHNER: Okay, the panel chair.
DR. SOX: To propose to the chair of the Executive Committee, who has the responsibility for approving the slate.
MS. RICHNER: Okay. There it is right there. Yeah. The panel chair and vice chair select the three external reviewers. The Executive Committee approves the two to three external reviewers.
Then the panel chair prepares a charge to

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the external reviewers, and the reviewers prepare the report to deliver to the panel executive secretary, and then the reviewers report on the evidence report is sent to panelists and posted on the Internet. Those are the steps.
DR. SOX: Right. So you asked the

question back to that earlier slide?
MS. RICHNER: Yes.
DR. SOX: Who consolidates? So the external reviewer comes in ten days earlier, the panel members take that into account as they go the meeting.
MS. RICHNER: Okay.
DR. SOX: The primary reviewer makes their report at the meeting.
MS. RICHNER: Those are two chosen people from the MCAC panel.
DR. SOX: Panel. It may be just one, but it will be one or two. The panel members obviously -- I mean, the public comment occurs. It did yesterday. And then who consolidates, as I see it, each individual panel member absorbs these inputs and decides on a vote.
MS. RICHNER: Okay. So those are all those sets, okay.

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Then, panel members receive and review the report. The panel chair assigns two panel members to be primary reviewers (inaudible, reading) and then the panel chair adds three to five content experts to the panel as temporary voting members. That's the other thing that occurs, that during the actual panel meeting we also have content experts that will be part of the panel discussion. Okay.
Just -- I don't have any comments one way of the other about this, it just seems rather cumbersome, but I think that the point that I'm suggesting here is, what if the two to three experts come back and they have conflicting reports about the evidence report?
DR. SOX: Then that's up to the panel members to absorb that.
MS. RICHNER: This is my last -- I have two more slides, but this one is about the evidence, and the panel's evidence evaluation guidelines using the evidence reports and reviews. And what I tried to do here was to say, and this goes back to the issue of the evidence reports and whether or not

there is, if it's adequate about effectiveness, then the magnitude, in reporting to HCFA. We also have in the guidelines that if the evidence is not adequate,

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is it sufficient? If yes, what I'm challenging here is, does it go back to, do we then show that it is effective, which is not necessarily the way I think that we are anticipating it should go. I think what we want to look at is if the evidence is sufficient right here, we want to determine the magnitude and then send the report to HCFA.

If evidence is insufficient or is sufficient no, where does this go? I mean, I tried to outline how you're describing the pathway of evaluating the evidence.

DR. SOX: Alan?

DR. GARBER: Randel, as I read the reports, sufficient and adequate are synonymous, and I don't recall any section that said it could be sufficient evidence but not adequate. Can you point us to where in the document it suggests that that is a possible classification? There is -- the section on what to do when the evidence is insufficient suggests things to do when the evidence is inadequate or insufficient.

MS. RICHNER: Right. Then it goes to your point where we say --

DR. GARBER: Yeah, but we never said the evidence is sufficient in any case then, it's just

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that there may be other options to consider when the evidence is inadequate or insufficient.

DR. SOX: Well, I think -- it sounds to me like there's some confusion that there may be two different ways to classify the information, and there is really only one.

DR. GARBER: But I didn't see where that appears on the document.

DR. HOLOHAN: On page 6 it says, when a panel determines the evidence is insufficient to draw conclusions about the effectiveness, it will not

attempt to classify the size of the possible effect.
DR. SOX: Would it help to just get rid of the word insufficient and use inadequate to be consistent throughout the document?
(Comments of assent.)
DR. SOX: Because I think the intent is that they are just one word, it either is or isn't that.
MS. RICHNER: That's right.
DR. SOX: So I will just go through and where I find insufficient, I will push it out and make the inadequate substitution.
MS. RICHNER: That would probably help. Okay. Once again, I think that's where I came into

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sort of classifying the three types of evidence that we're looking at, or decisions that should be made to be adequate or sufficient, insufficient or promising, insufficient or not promising, and what happens then ultimately at the end of the process. I would say the most -- okay, I'm done, but I would say that I think that my most serious concern, once again, is that none of these processes have any time limits whatsoever associated with any of it, and it could really go on for months and perhaps years, as evidenced by, you know, certain procedures that have been through a long grueling process through HCFA. So, I'm hoping that somehow we can put some boundaries on what this process means.
DR. SOX: I think a time line will be very helpful for communicating with everybody, and it shouldn't be a difficult matter to piece one together from this document, as you really have already done. Joe?
DR. JOHNSON: Isn't the time line to a large degree going to be determined by HCFA's need, as far as your setting some of the guidelines on time frames.
DR. TUNIS: Yeah. I mean, a lot of --
DR. JOHNSON: As far as urgency, or maybe,

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you know, it's not real urgent but needs to be done and you construct the time lines.

DR. TUNIS: Right. I mean there are again, newly imposed in statute some mandatory time lines, but it only applies to things that don't go out for a technology assessment. Once something goes out for a technology assessment, the time frames are not defined as Randel says, and whether or not the Executive Committee wants to venture into trying to define time lines, is an interesting question that there would be pros and cons too.

I mean, the other thing I have to say about that is we're at least on the hook now for writing an annual report to Congress about how long it's taken for each decision and why, and so there is at least that level of sort of newly imposed accountability for the time frames for every single coverage decision we make.

DR. HOLOHAN: And historically, generally the smaller the evidence, the greater the time it takes. I mean, nobody spends a lot of time debating about total hip replacements.

DR. SOX: Right, or hip pinning for hip fractures, right?

DR. HOLOHAN: Right.

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DR. SOX: Alan.

DR. GARBER: Well, on this issue of how specific we should be about the time line, it's clear that we need to send a signal that we want this process to be as expeditious as possible, but we have also created a new -- we have modified the interim guidelines in some ways that are fairly substantial, and in particular the review steps, and as a practical matter we could proceed and put down time estimates or time goals right now. As I have tried to work with the guidelines, it has become clear to me that there is a big advantage to getting a little experience with them before we try to write down things in detail.

So, I would like to make a suggestion that we work toward the goal of incorporating a time line

in maybe the next draft of these interim guidelines, but gain some experience with these, or whatever we ratify today, before we put in too much detail on the deadlines for each step of the process, because I think it's not going to look good and it won't serve our process well if we find out that for some reason or another, some steps of the process with the time we gave it just aren't feasible.

DR. SOX: Leslie.

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DR. FRANCIS: I would hope that the way we take all these points that are being made in the discussion is that we have almost -- we have our own little set of annotations, the things we're watching for as the process goes on for the next iterations of it, so that we are watching closely for example for what the times look like and what seems reasonable and what we can push and what we can't, and so on. But that, I would make that same point for all the critical points that we have made so far.

DR. TUNIS: One other point just also to raise here is that there is kind of a presumption in these guides that the only thing that would ever come to the MCAC would be a topic that has been assessed externally by a contractor body and in fact there would be situations in which we might want to come to MCAC where we reviewed a topic internally, but still want the MCAC to deliberate, and that sort of pathway isn't really framed here, although you can imagine that we could just pretend that, you know, the HCFA coverage group is essentially substituting for the contractor and go through exactly the same steps. What we have been reluctant to do in the past of course is produce a HCFA report that looks like a contractor report, again, for issues of not wanting

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to look like we've prejudged the issue prior to it coming to MCAC. But it seems at least that issue needs to be thought through a little bit, you know, what do we do when we don't hire an outside contractor but still want to bring an issue to MCAC.

DR. GARBER: Well, Sean, given what you just said, HCFA is not identical to an outside contractor, but would we be wrong to say contractor could refer to internal staff reports, et cetera, from HCFA under certain circumstances, or would that be too misleading?

DR. TUNIS: I think we could propose that; we'd have to just think about it a little bit more, because again, we would then be presuming that we'd ultimately bring forward some report to MCAC to be discussed as if it were produced by an outside contractor, but everything else would be the same, which seems fine to me. I just haven't thought through all the ramifications of it.

DR. HOLOHAN: What you might want to do is provide the evidence and not a HCFA report. Presumably the report was based on information. If you provided the information to MCAC, it removes the presumption that you prejudged, unless someone believes you've selectively provided it.

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DR. TUNIS: Right, but we're going to want to provide a summary of the information unless you just want us to provide, you know, the four volumes of material.

DR. GARBER: Absolutely not. We know that doesn't work.

DR. TUNIS: And any version of a summary is subject to some conditions about, you know, what's included and how it's interpreted and all that stuff.

DR. HOLOHAN: But it's also public.

DR. TUNIS: Right.

DR. GARBER: Could I make a suggestion on this point?

DR. SOX: Bob has been waiting a while.

DR. GARBER: Okay, sorry.

DR. MURRAY: Just a comment to Sean's hypothetical scenario just a moment ago. It's my understanding that what we're talking about are recommendations, that's what they're titled, or they're guidelines, these are not hard and fast rules. We are not as an executive committee going to

reject an issue that comes before us because it didn't follow precisely the rules that we're setting down.

And I look back to the issue of, or the

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discussion of PET scanning just a couple of months ago. That violated all of the rules. It came directly to the Executive Committee without going to the panel, and I would imagine that situations may come in the future that we are not going to follow 2.A, 2.B, 2.C, 2.D.

DR. SOX: Right. Alan?

DR. GARBER: I just wanted to suggest if the, that if HCFA were to do an evidence report or compilation of information, that they should be held to the same standards to which we would hold external contractors, and I think we should have a statement to that effect in this document.

DR. SOX: I would like to step back for a second now. We have heard from everybody from the panel and the take seems to be what we've done so far looks good. Several people have mentioned some things that they would like to change, but my take was that with the exception of Randel, who prepared a pretty detailed analysis, most everybody is pretty happy with these the way they are, and perhaps even more so with learning that this is an ongoing work in progress and that until we actually try these out completely, you know, from the start, that we're really not going to be able to take them very much

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farther in the abstract.

So with that as a sort of preliminary, I wonder whether we could divide, in trying to get to a point of approval, some people want to simply make word smithing suggestions, and I'd suggest that they judge or not -- don't rise to the level of really requiring panel approval, and I suggest that you simply provide those to be me and I will make those changes or give you an accounting of why I don't.

Others may have some things that they

would like to see changed now as opposed to a year from now, and they think that they might in some way be sufficiently substantive to require discussion and endorsement. And if it's agreeable to you, I would like to go on to that second group, with the goal of trying to get to a vote to approve fairly soon.

I also note that we will want to have an opportunity for a public comment, scheduled or otherwise, before we take a vote and to be able to respond to that, and I guess that's it.

So, I guess now I would like to call for comments that people would like to see some change now and that they feel rises to the level of significance that really requires some discussion now.

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DR. FRANCIS: Do you just want to go page by page?

DR. SOX: Beg your pardon?

DR. FRANCIS: Do you want to just go page by page?

DR. GARBER: No.

DR. FRANCIS: No? Or do you want to just do it?

DR. SOX: Well, my sense is that people are generally pretty happy and that we will just sort of get people who want to make a comment to make the comment, we'll debate it and --

DR. FRANCIS: I know this is a flash point, but the paragraph on page 4 that reads, although a body of evidence consisting only of uncontrolled studies, whether based on anecdotal evidence, testimonials or case series or disease registries without adequate historical controls is never adequate, in some cases the panel will determine that observational evidence is sufficient, that's just inconsistent.

DR. GARBER: How do you want to --

DR. FRANCIS: Well, the way it seems to me to be inconsistent, unless I'm misunderstanding it is, it says evidence is never adequate, nonetheless

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the panel can consider it adequate.
DR. GARBER: No. It says observational --
DR. FRANCIS: Well, that may be where the adequate-inadequate sufficient-insufficient --
DR. GARBER: The first statement is a subset of observational studies that lacks adequate control controls. The second statement is other observational studies. There is no inconsistency.
DR. FRANCIS: Then why don't we say other observational evidence is adequate.
DR. SOX: Or observational evidence with controls?
DR. FRANCIS: That some forms of --
DR. SOX: I think that's the intended meaning. Alan, do you?
DR. GARBER: Well, all right. Well, the key issue is that it is either -- evidence that is on its face adequate always has evidence under adequate controls and maybe that's the part that needs work, so maybe uncontrolled versus controlled. So if we were to say that the panel will determine that observational evidence with controls is sufficient to draw conclusions about effectiveness. Would that do it for you?
DR. FRANCIS: That certainly makes it

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consistent. I don't know if it captures what you wanted, but I mean, I just didn't understand that paragraph when I read it.
DR. SOX: Okay, good. Other comments about either clarification or new ideas or changes?
MS. RICHNER: When we're suggesting the with controls, that can be -- that that includes the different types of --
DR. GARBER: Yes, it can still be called controls of some kind, historical, case control, et cetera.
DR. BROOK: Are you preventing a clinician from getting up and saying I treated these patients this way and they got better and I treated these patients this way and they didn't. That's control

and now they can decide what they want to do with it.
MS. RICHNER: That's right.
DR. GARBER: Well, it doesn't mean it's always adequate, it says sometimes adequate. If you like the doctor, it's adequate.
DR. BROOK: Well, I treated 12 people with SDE with antibiotics and 12 without, and the ones with SDE, 50 percent of them lived with antibiotics and 50 percent didn't. I have no records.
DR. SOX: Barbara.

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DR. McNEIL: I just had a question for clarification and maybe it's for Sean, and I definitely don't want to be micromanaging, but on page 7 we talk about HCFA provides coverage on a provisional basis, and then a bullet, it would cover the technology only when it is being used in the context of an approved study. Isn't that already being done as part of the Medicare rulings in November, or last June rather, in term of Medicare --
DR. GARBER: No.
DR. McNEIL: No?
DR. GARBER: It's the routine care components.
DR. TUNIS: Yeah. That doesn't cover the cost of the investigational item.
DR. McNEIL: Wait a minute. Give it me again. What is the yes?
DR. TUNIS: Sorry. The clinical trials coverage policy that was implemented in September only covers routine costs associated with the clinical trials; it doesn't cover the costs of the investigation items.
DR. GARBER: Yeah. It covers everything but.
DR. TUNIS: Everything but. And this

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whole section about -- well, it's sort of, I guess a wish of a direction that the EC would like to see HCFA go, as opposed to someplace that we could get any time soon, I guess.

DR. McNEIL: No, I wasn't questioning the validity of it, I was just thinking it was redundant.

DR. TUNIS: I mean, I think that's the function of it.

DR. SOX: Yes, it's a direction we hope things will take eventually. Other? Daisy?

DR. ALFORD-SMITH: I think you have already have it, but I just wanted to make sure again. There was something that I was concerned about in reference to the preface more so than anything else, and it goes back to what I had initially stated, and somewhere I believe we need to clarify that although we provide advice on a scientific and clinical question, that it's inherent in this process that we also recognize that the committee provides advice or assists HCFA in setting policy. I mean, that's the reason for it. We don't speak to providing this information regarding coverage.

DR. SOX: Well, I mean, I believe that the first sentence of the whole document states where we

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were at right now, that we don't tell HCFA that this ought to be covered.

DR. ALFORD-SMITH: No, no, no, that's not what I'm saying.

DR. SOX: I'm sorry. I'm missing it then.

DR. ALFORD-SMITH: My interpretation of this gives me the inclination that it is limited from a technical perspective without any sensitivity to the needs of addressing the issues for the general public.

DR. SOX: What, could you -- I think I know what you mean by technical issues. What I'm not sure I understand is what you meant by the last part, the general needs of the public.

DR. ALFORD-SMITH: I am saying that it appears to me that we have been convened to provide advice based upon scientific and clinical questions, without a sound statement as to why there is a need to provide advice on those scientific and clinical questions.

DR. SOX: So, are you saying that there is nothing, our charge does not include deciding whether this is an important issue to address in the first place?

DR. ALFORD-SMITH: Yes.

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DR. SOX: Okay. We basically do what HCFA tells us to do. We don't decide to, you know, to turn it down because we think it's unimportant.

DR. ALFORD-SMITH: No, no, no, I understand that, but in reviewing some of my notes, one of the things that struck me was HCFA's response to their attempt to alleviate the fear that there was too much, the information was going to be too scientifically oriented, you know, and that went out to the media in some way. There was a concern there for that reason. And so, it doesn't appear to me as if we're speaking to how to be consistent with what they have already had to address in some way.

MS. RICHNER: I think when MCAC was originally formed, the whole idea was to bring in policy makers, to bring in scientists, to bring in the medical profession, to bring in sort of a cadre of different perspectives on the issue of deciding coverage. And what's lost in this, I think is what she's saying, is that it's become so narrow that we're just focused on the scientific evidence and we've lost that spirit of what we, you know, as a very diverse group, bring to the table in terms of decision making. And that's something that is a shame in a sense, that we've sort of lost that

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perspective.

DR. SOX: I wish you could have been here yesterday. I think your mind would have been perhaps set partially at ease. I'm thinking, Daisy, it says provide advice on scientific, and I have underlined, and clinical questions. And once you take it away from strictly scientific questions and add that and clinical, that --

MS. RICHNER: Well, it goes beyond that,

though. In the policy, in social research, in bringing in all these kinds of issues from a consumer advocacy position, and what matters most to the Medicare population in lots of different perspectives.

DR. SOX: Well, you know, ultimately our job strictly speaking by what we've written here is to decide whether the evidence that the candidate technology -- whether the evidence is adequate to decide if the candidate technology is an improvement over what was there before and if so, big effect or small effect.

MS. RICHNER: Right, I understand that, and we have addressed that in a sense by providing input for this public to provide different perspectives, and that's a real move forward from

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where we were, you know, eight, nine months ago. So I think, you know, Daisy from that perspective by posting this on the web, by being able to provide, you know, get the different perspectives, will be a part of this decision making process a little more effectively.

DR. SOX: And we are going to get a lot of input about, at least about the size of the impact, because that's what the public is telling us, you know, this has made a big difference in my life.

MS. RICHNER: Right. But maybe the entrance to this, or the introduction, could be a little enhanced about what we're intending to do to kind of consult to HCFA.

DR. SOX: Alan.

DR. GARBER: Well, I think it is supposed to be an inclusive process to the extent that there should be ample opportunity for public input, and that's implicit throughout this document. But I certainly think that if Daisy or anyone else had suggestions about ways to make this more explicit a principle, that would be very welcome.

In terms of the overall operating principles of the whole MCAC process, if the issue is, should the MCAC process be focused on scientific

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clinical evidence or should it be focused on something else, I think we have had numerous discussions where the Executive Committee has come down, this is about scientific and clinical evidence, and I think implicit in there is the belief that we serve the public best by trying to really answer the question, does this technology work, does it improve health outcomes. We do not necessarily serve the public by answering questions like is this popular, do people want it, and that is a real judgment that we have made. So if the question is, have we incorporated enough about political, social considerations and so on, I would argue that we have considered it and decided that's not what we do best, the way we best serve HCFA is by evaluating the scientific and clinical evidence, and we're doing that with the intent of serving the public well.

DR. ALFORD-SMITH: That's my point right there. You just answered it. That was the statement; you said what's the intent.

DR. BROOK: Can we add a second sentence after the first sentence that says, after we say provided by, it is hoped for or expected that the MCAC process will be to improve the health status of the Medicare population and to reduce adversity in

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health status by ethnic and gender, and state, or whatever we want to say, to make it more of a one program one coverage, and these two things, that's really our goal, that this is what the outcome of what this process is. It's not going to say that we're responsible for it, but it's expected the outcome of our advice will lead to those kinds of general outcomes. Is that what you want, Daisy?

DR. ALFORD-SMITH: Yes.

DR. BROOK: Yeah, that's what I thought.

DR. SOX: Well, Daisy, perhaps you would draft a sentence to go there.

DR. ALFORD-SMITH: I think Bob just did.

DR. SOX: Well, would you write it down so

-- Alan?
DR. GARBER: Well, I actually think that we should say very simply that the intent of this process is to help identify effective medical goods and services, and insure that the Medicare population has access to them, and by doing so help to insure that the Medicare population has access to them.
DR. HOLOHAN: I like the phrase Alan began with the last time by saying, this group serves the public interests best by.
DR. ALFORD-SMITH: The intent.

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DR. SOX: Well, Alan, would you draft -- would you just write something that I can --
DR. BROOK: That's less broad than what I suggested.
DR. GARBER: Yes, and that's deliberate.
DR. BROOK: And I would prefer the broader statement that it's expected that the outcome of the MCAC process will lead to improved health status of the Medicare population and reduce differences in health status by Medicare, by the state in which the Medicare enrollee exists, by the gender of the Medicare enrollee, or by his or her racial or ethnic characteristics.
DR. SOX: Well, it's good to want that, but really, we don't really address that.
DR. HOLOHAN: Well, Bob, we disagree. I think mins is more broad than yours, frankly, because I think what we do affects people who are not necessarily Medicare beneficiaries.
DR. BROOK: Good. Then let's talk affecting the U.S. population, I'll change Medicare to U.S., but I think we ought to have health status in it and I think we ought to have the dual goal of reducing, you know, issues --
DR. ALFORD-SMITH: My intent was not to go

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that far. However, I think it should be related in some way to outcomes.
DR. SOX: Alan is working on a statement

and he'll read it, and then we will see if it hits the spot, and then we will move on.

DR. FERGUSON: Hal, aren't some of these things encapsulated in the MCAC charter?

DR. BERGTHOLD: This isn't a charter.

DR. FERGUSON: It's not?

DR. BERGTHOLD: No, this is just our guidelines.

DR. FERGUSON: No. I'm saying that what Daisy was talking about, some are encapsulated in the charter of this committee. I thought they were. I don't have the wording in front of me.

DR. TUNIS: We'll try to get the charter and see what the language is. I'm not recalling that this is, you know, that this has sort of been dealt with in great depth in the charter.

DR. SOX: Barbara?

DR. McNEIL: Well, I was going to suggest that we tweak out what we think is in our charter and that we not be too expansive unless it's in the charter, because we don't want to be held accountable for something that we can't control. So while it

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might be nice to prevent racial and geographic inequities, I'm not sure that the kinds of data that we are being presented and the decisions that we make are necessarily dominant forces in doing that.

DR. SOX: Yeah, we do what we do, and we need to do it well. Alan, do you have something?

DR. GARBER: Well, I'll try this on you. This process is intended to serve the public by identifying medical goods and services that improve health among Medicare beneficiaries or that improve the health of Medicare beneficiaries.

DR. BROOK: I would add, and reduce diversity, and reduce differences.

DR. GARBER: That would be your proposal.

DR. FRANCIS: Reduce discrepancies.

DR. SOX: Okay. Why don't we -- so you have made a proposal that this is what we are going to add, and we are going to vote on this --

DR. GARBER: Right.

DR. SOX: -- as a way of resolving differences here. Now, does anybody want to amend it?
DR. BROOK: Yeah. I want to add a clause that says, and reduce differences.
DR. FRANCIS: The issue there really is

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the way local carriers can make arbitrary -- you know, you can have one here, one here and one here, and I -- the difference seems to me to be too broad in that.
DR. BROOK: You mean variations?
(Inaudible, people speaking at same time.)
DR. SOX: Listen. Listen. Let me propose a process here --
DR. BROOK: There's variations in health status --
DR. SOX: -- for getting a sense of the group's opinion about this, okay? So Alan has made a proposal and Bob has now made an amendment. Could you lean forward to the microphone and say it so we can all hear it, Bob?
DR. BROOK: And reduce variations in health status by where you live or who you are.
DR. SOX: Okay. So that's Bob's suggested change, and we are not now going to vote about whether to add that to the end of Alan's sentence. Everybody who favors Bob's change, please raise your hand. One, two, three four, five. Those opposed? One, two, three, four, five, six, seven. So it fails, seven to four or five. So we will incorporate your sentence as the second sentence in this document

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as you suggested, unless there are any other suggestions. Yeah, Bob.
DR. BROOK: Yeah, I want to vote no on that. I want to go on the record to say why I'm voting no is that the real goal of the federal policy ought to be, anything it does ought to be evaluated on how it reduces differences by where you live, this is a federal government, or your racial or ethnic

characteristics, or your gender. That's the real test of a public program. And the U.K. Has agreed to do this, and every other developed country is moving in that direction, and we ought to include that statement if we're going to include any statement like that in our document. I want that in the record.

DR. SOX: Okay. So let's now vote on Alan's statement. Do you want to reread it please, Alan.

DR. GARBER: This process is intended to serve the public by identifying medical goods and services that improve the health of Medicare beneficiaries.

DR. SOX: All in favor of inserting that sentence as the second sentence in the preface, please raise your hand. Everybody's eligible to

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vote. Anybody opposed? One opposed, everyone else votes in favor.

I think this might be a good time to call for public comment on what we're doing here.

DR. BROOK: I have one other comment on the document as a whole that I want to get in the record, because I don't think we want to address it. We're missing the central issue of technology assessment, and that is the frequency and how often that it's done. The major conclusions up to now, this document addresses just, "whether it's effective," and it presumes that ever once. The real issue for Medicare coverage and the advice that HCFA really needs is why are only six physical therapies allowed after you fracture a hip, or four, you know, edema reduction therapies after you have breast cancer even if you have it, or six therapies in a swim pool done, or four electrical stimulations or one.

It's the frequency of most of these technologies, whether it's a PET scan or whatever, that's going to drive eventually health status and cost in the Medicare program, and we're doing a very small percentage of the job if the outcome of this

process is to just say that the evidence is slightly

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better, or we're going to use it for once. The guidelines don't address that point about the responsibility of the committee, and I would just indicate it not to discuss it today, but hope that sometime in the future we can have a much nor sophisticated process when it comes to those kinds of questions, because that's where the money is and that's where the controversy is, and that's where local control will defeat, you know, the intent of the evidence and what this Committee has been all about.

DR. SOX: Yeah. Somehow we need to provoke more studies on this, and the question of how to do it best is one that we should address, but perhaps not now. We don't talk about it because nobody studies it. So, I'm going to call for public comment now, and then we can continue our discussion. So, is there anybody in the audience who would like to make a statement?

MS. CONRAD: Greg Robb.

MR. ROBB: For the record, my name is Greg Robb. I represent the Advanced Medical Technology Association and I am a consultant here on their behalf.

The guidelines that you are taking up

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today appeared on the HCFA web site in the afternoon yesterday. I was to come here and talk about a previous iteration, and AdvoMed advised me not to talk about the content of the therapeutic or the diagnostic guidelines in particular, but to use my best judgment as to what was posted and in light of previous positions.

I would like to go back to these guidelines and say what you have done in taking up the guidelines, you have sort of switched between the guidelines and the role of MCAC. The last motions that were considered go in that direction so I'll slide over to some of the points I could make this

afternoon as well.

With respect to the guidelines, though, the industry's role has always been that this whole Medicare coverage process be open, predictable, timely, with the opportunity for public comment. I was particularly pleased, and I will be advising my client to be very pleased with the discussion that took place today on opening up the process, involving the public, use of web site in reacting to these evidence reports. That level of interaction is very healthy and I was very pleased to hear that discussion.

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On the other hand, with regard to the predictability and the timeliness of the Medicare coverage process as a whole, industry still would have concerns. If you go back to the Medicare coverage process as a whole, the notice that appeared in the April, I believe 27th, 1999 Federal Register never did put a time frame or a targeted time frame on Medicare Coverage Advisory Committee review of new technologies up for consideration in the coverage process. There were no time frames associated with the possibility of HCFA asking for a technology assessment. The notice in April of 1999 also held out the possibility that HCFA could ask for an assessment and MCAC itself could ask for an assessment.

My general sense of the discussion that's going on here today with regard to evidence reports would constitute a de facto technology assessment in terms of that notice. So there is a level of confusion of me, and I come to some of these meetings. The public, I think would have a little bit more confusion, and I think the AdvoMed constituency is terribly confused as to what exactly the hurdles are, what the time frame is if you were to request a national coverage decision. I feel

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consumer groups would think that as well.

So we have this issue of what is the goal

here. I see good value put in here in these evidence reports. I see where you're going, I like the public process involvement. I don't know what it means in terms of a review process. Randel started to go down that route with her slides and that raised a lot of troubling questions about how long all this will take and where the money is going to come from to staff it.

With regard to another factor which you will take up this afternoon, I wanted to get to the situation where we have, if you're a manufacturer, you see a two-step review process. You see a process where an issue is vetted at the panel level and relitigated, if you will, at the Executive Committee level. I wanted to point to the BIPA legislation which permits the Agency to ask the panel to review and to make a coverage decision based on panel deliberations.

Now that would not mean that this Executive Committee wouldn't have a role. They could certainly provide guy as it is doing, it could manage the resources of the entire process, it could weigh in as well, it could comments on how well the panels

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have deliberated and documented their findings, but the concept of a two-step process is a bit troubling in terms of time, and I wanted to raise that as well.

One other issue as you talked about, as you slipped over into the MCAC role and what your charter is, it was to advise the Agency on making decisions as to whether services are reasonable and necessary. That is also laid out in the April 1999 notice. It's to make advice to the Agency on whether coverage decisions should be made.

The notice doesn't say that the only role of this body is to weigh evidence or to find that the evidence is conclusive, or decide what is evidence. It talks about advice on coverage.

I would like to point out that the BIPA legislation also spoke to that, and let me read to it. It said that Medicare coverage decisions should be made after considering, quote, applicable

information, including clinical experience and medical, technical and scientific evidence. It doesn't say only peer reviewed studies or studies that will be published in journals, it said evidence. It said evidence broadly, and it said information. And I go back to the, again, the coverage notice, which talks, the whole role of MCAC was to have open

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public meetings, anyone can present, and based on all of the presentations, advice would go to HCFA.

DR. SOX: Thank you. Perhaps you would like to stay up there for just a second. Are there any questions anybody would like to address of Mr. Robb? Thank you very much.

Would you come forward, identify yourself, tell us whom you are affiliated with.

MS. CHRISTIAN: My name is Martha Christian and I am a health policy analyst with EMPI, and many of you are aware that our company recently went through this whole process with our technology for pelvic floor electrical stimulation. We are in a rather unique position to discuss this simply because we have been through this.

And I have to first of all applaud both staff members at HCFA and both the Medical Surgical Panel and this panel itself in looking at a process that has been in a constant state of flux, and I think what we're trying to do here is a good thing. We want to have a more predictable consistent open process, and I think I see a lot of good things in the document that we have been discussing today.

I have a couple of concerns, though, that I think is important to discuss. First of all, if

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you look at the notice of proposed rule making that HCFA laid out earlier last year and is in the process of -- and received public comment, one of the questions that was discussed or raised was, should there be varying levels of evidence for different types of technology? What I see in this document is that unless you have the gold standard, randomized

control trial, you're dead at question number one.
The reality is, many small medical device manufacturers cannot afford the kinds of studies that you're asking for in this document, which basically essentially has the effect of limiting access to technology to many Medicare beneficiaries, particularly those devices and procedures that are low cost. If they are low cost, there is not a lot of money in it to fund the kinds of studies that you're looking for.
So I guess I would caution both HCFA and this Executive Committee of making these guidelines too restrictive. And one suggestion I have for dealing with that is essentially to, you know, ask question number one, is the evidence adequate based on what we would absolutely love to see, but I think there has to be recognition in the process that most technologies, particularly existing technologies that

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may become subject to further review, will not have this level of evidence. Does that make them unworthy of consideration for coverage? Absolutely not.
So what you need to incorporate in this particular document is that you can go to question number two, you know, is there some value in this technology? And that's where the spirit of the MCAC charter comes in in terms of saying, you know, let's look at all of the evidence.
And one of the things that I have to congratulate HCFA on is despite the fact that it was purely an evidentiary review of our technology, they looked at all of the evidence. They looked at consumer input, they looked at the input of the clinical societies, and I sensed the frustration, and we all had the same frustration of those people who sat on the Med-Surg Panel and discussed PFS and biofeedback and found that we can only look at the evidence, I mean, the specific scientific evidence. They were frustrated.
Fortunately HCFA in their wisdom, looked at all of the evidence and we came up with I think a good coverage decision, one that looked at, you know,

some of the limiting factors that you discussed earlier with some of the other technologies today,

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and that was I think very useful. So just be very careful when you're looking at these evidentiary guidelines.

The second point I would like to make concerns some of the time lines. I think Randel raised some very important issues. And one of the things, just from a practical perspective, I see when you're looking at releasing the evidentiary report two weeks prior to a meeting, let me talk about that a little bit.

That happened to us in pelvic floor stim. We didn't see the evidentiary report until two weeks prior. As someone who had to prepare for that, I had two weeks in which, one, we got the questions at about the same time, so we didn't even know what questions were being considered. We didn't get the report. There were certain studies that weren't included in the report. We had to schedule speakers that were to come before this panel; many of those speakers were physicians. You guys all know your schedules. Could you clear your schedule in two weeks in order to come and testify before a hearing without substantially inconveniencing yourself and your patients? I think that's a real concern.

Secondly of all, as a panel member -- or

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first of all, as a speaker, you're probably going to get from 5 to 15 minutes to present your information. Many of the issues that are often raised in these TEC assessments take a lot more explanation than 5 to 15 minutes. And so it's important that you as a panel member be able to have an opportunity to review those written comments that are submitted after the posting of the evidence report on the web so that when we come to the panel meeting, you already have the information and there can be a discussion of what are the points of confusion, instead of us trying to say, this is all what's wrong, in five minutes, and then

have the panel trying to digest that information in relationship to the other materials that they have.

So I believe that that time frame is something that really needs to be evaluated, and whether or not that's done by this document or by HCFA staff, I think it's important that the message gets out that we need more time. We are all interested in having a good and fair hearing on the subject at hand, and we can't do that unless we have adequate time.

The other thing is the posting on the web. The timing, I think the gentlemen from AdvoMed made the point that this document that you're looking at

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today wasn't posted on the web until yesterday. There is significant problems with HCFA getting their documents put up on the web, even if HCFA staff is sending it to them. It's outside of their control when that documentation gets on the web, so I think that you need to be aware that just because we want it posted on the web, it's submitted for posting on the web, it doesn't always get there. And I know that causes much consternation to the HCFA staff that are sending it to those people who put it there. So, understand that there are other issues that may impact the availability of the information, so I guess that's all I have. Thank you.

DR. SOX: Thank you very much. Any questions for the last speaker? Bob.

DR. MURRAY: This is not a question, just a comment, that it appears to me that we have a dilemma, that on the one hand the -- we take too much time, MCAC, the entire coverage process takes too much time; on the other hand, we're not giving the petitioners enough time. I don't know how we can answer both of those complaints at the same time.

DR. SOX: Yeah. You might have added that it is the petitioners who are complaining about the length of the process, so there is a problem. But in

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general, I think trying to get stuff on the web as

far ahead of a meeting as possible is that something that HCFA ought to be striving to accomplish, and it does make good sense. Randel.

MS. RICHNER: I really appreciated Martha's comments, and I think this was a real practical use of the system, and we've made progress since then, and I do differ in terms of looking at -- I think we have made tremendous progress in looking at evidence beyond double blind randomized control trials, and that was a lot of our discussion today, so I think there is a lot of room for different types of evidence to be evaluated.

But, I do have one anecdotal note about that particular technology. Their first contact with national HCFA regarding this technology was 1991 and so it took them nine years to get a coverage decision on this, and in fact they went back and forth with HCFA, and I have the whole chronology here, of asking what studies should they do, HCFA counseled them about what study they should do, they did the study, they came back, they said well, that wasn't exactly the right study. It was just unbelievable, so this is almost the poster child for what can go wrong in terms of this process. Now I know there's been lots

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of improvements since then but this was really truly a miserable experience for that particular technology.

DR. SOX: Before we continue discussion, I want to give a weather report. The weather has come in, and so I gather visibility is very limited, and so we are trying going to try to get to the point of a vote as quickly as possible. Then Sean is going to say a few remarks about the future of MCAC and we are going to postpone our discussion of the future role of MCAC until another time when it's more propitious. So that's the game plan, and I think it's quite possible we could be out of here by noon and people can do their things in terms of trying to get home. Bob.

DR. BROOK: I have one comment. I was a little disturbed by the last person's comment that

the studies in the contract report had not included the ones, or not looked at the ones that they knew were available. That bothers me and if that is the case, maybe we can fix that in this document by suggesting that the -- there must be some way of notifying people of the questions and the contractor who's going to produce the evidence report, so that industry could, you know, immediately, you know, make

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sure that whatever studies they want to get in front of the contractor could be sent to the contractor. I mean, I don't know whether there is anything in our document that -- I mean, we ought to proactively deal with that problem is what I'm saying.

If there's some way of adding a sentence somewhere in that document, Hal, of the process that says we ought to make industry aware at the very earliest that these are the questions, this is what's being discussed, this is the contractor, and the contractor would like to receive any documents that you have, that you want to submit as soon as possible, so that it be included in the evidence report or evaluated, would be my suggestion to the second commenter. Can we do that? Is that there already.

DR. SOX: We already have a lot of language in there about posting the key questions at the earliest possible stage and that's clearly a signal to industry to --

DR. BROOK: And do they know the contractor? Is there anything we can do? I just wanted to --

DR. SOX: Yeah. There is language in there about who the contractor contact person is.

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DR. BROOK: Okay. So it's all done, so it's really --

DR. SOX: I think it's in there.

DR. BROOK: So there's nothing we need to change.

DR. SOX: Yeah. Alan?

DR. GARBER: I'd like to make a process suggestion.
DR. SOX: It would be welcome.
DR. GARBER: The process suggestion is that the committee vote to accept or reject the current document in general, subject to further revision, and the process for further revision I suggest is that the detailed comments be submitted to perhaps Hal and incorporated by the methods working group, writing group, whatever you want to call it. They produce a document that will then be distributed to the entire Executive Committee for comment and acceptance.
And I don't think this requires formal vote, because these should at this point be basically word smithing changes. And if it turns out there are some major issues, then we can subject it to a vote, perhaps at the next executive committee meeting.
DR. SOX: So your proposal is we would

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take a vote now to accept the major thrust and then we would word smith, but not require a future vote.
DR. GARBER: Yeah. I'm basically asking that the writing group have the discretion to produce the document, which however would then be distributed to the entire executive committee before being made available to the public.
DR. BERGTHOLD: Can we ask that changes be put in italics or something, so that we don't have to try to figure out what they were?
DR. SOX: They are currently in bold face, Linda. They are in bold face now.
DR. GARBER: By some comparable method.
DR. SOX: By some comparable method. Would you like to suggest a time frame for that, Alan? I think it's really important to get this stuff up and out of here.
DR. GARBER: Yeah. I would suggest that your individual comments be submitted to Hal within the next 10 days and that the writing committee be given one month after that to produce the final document.

DR. SOX: So we might say six weeks to have completed the revision process and then another two weeks for further comment, but we'll aim to have

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something that we can live by for a while by two months from now.

DR. GARBER: Right.

DR. SOX: Does that sound reasonable?

DR. BROOK: I thought we just did that. I just don't know why we can't -- this is an interim document -- why we can't take all of those word smithing changes and put them on the agenda for the next document, and we can't just pass this document and get on with it. We've made the changes, the major changes that we talked about. We have gone over this now five different times. Everyone is going to want to do it a little bit differently. When it goes back for you, we're going to have to go back through a public response, an executive committee response. I mean, haven't we done -- we've done this three times. It's an interim document. I mean, all of us have something we dislike with it, and we always will, so why don't we just pass it?

DR. SOX: I think there needs to be an understanding that any changes will be minor word smithing changes. Anything that's really substantive, let's talk it through and get it passed so that -- I agree with Bob. I don't think -- we shouldn't spin this out, but I think there should be

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an opportunity to tweak it a little bit.

DR. GARBER: Maybe I wasn't being clear enough. What I have in mind I think is similar to what Bob is saying. This should only be word smithing changes that we're voting to approve or not approve today, but the idea is that Executive Committee members would have an opportunity to review this, and if they see that a change in their view in fact is not simply word smithing but a substantive change, they would have a chance to express their disapproval.

MS. RICHNER: I still am very concerned once again about the timings, and that is a big issue, and I'm concerned, are we going to do that in the methods subgroup in terms of putting some timings in there?

DR. GARBER: No. I think that the way the document stands it does not have time lines and if you think it should, it has to have more detailed time lines, you should probably vote down this document, because that would be a substantive change.

MS. RICHNER: It is a substantive change, and also, there are timings that are described in here in a couple places which I have disagreement with. I mean, you either have to take them all out

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and review, think of it differently. I mean, it's very important Hal, I'm sorry, but timing is a huge issue here.

DR. SOX: I know it's a huge issue. But, my suggestion is that we develop a time line for discussion and approval at our next executive committee meeting, we not try to do that now. Let's get this document out along the lines of what Alan has suggested, with a -- and hold our hands to the fire to get a time line for discussion and vote at our next meeting.

Ms. RICHNER: Time lines associated with the process?

DR. SOX: Yeah, along the lines of what you were doing with your work, your summary.

MS. RICHNER: Okay.

DR. SOX: Linda.

DR. BERGTHOLD: Do we have any EC meetings scheduled at this point?

DR. TUNIS: No.

DR. BERGTHOLD: Do you have any idea approximately what month?

DR. TUNIS: Probably late spring or early summer, so Junish or something; that's a very wide target.

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DR. SOX: Okay. I would like all comments to be focused on this process question so we can get to agreement on that, and then I want to vote.
DR. BROOK: What's the process question?
DR. GARBER: Could I just clarify the process then please?
DR. SOX: Yes, please.
DR. GARBER: It is that it would be, we would be approving or not today, and these rules would remain -- or interim guidelines would be in effect as approved when revised, unless members of the Executive Committee said not that they disagreed with something we already discussed, but they thought that some of the changes made changed the meaning in such a way that it was a substantive change and therefore it does not correspond to what they voted to approve today.
DR. BROOK: I basically think we need interim guidelines. I don't -- I want to speak against that process. I think the only thing that will work at this moment is to give Hal the authority, whatever -- if they are substantive changes, those people ought to vote down and we ought to then know that we don't have agreement on this thing. If we have agreement on substance change,

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anything that's considered word smithing ought to be sent to Hal, no working group meetings, no other thing. Hal has the right to change any word he so sees and that document as Hal modified it, it would be in Hal's judgment whether that's substantive or not, and we will have a final document which will be our interim rules. I don't believe we can recycle this because we're not going to get anywhere. I think we ought to vote up or down whether we agree on the substance, and then we ought to delegate to Hal the ability to make -- Hal and HCFA staff, to make any changes in the document that are at the word smithing level. If it's really word smithing, that's all it takes.
MS. RICHNER: What's the rush?
DR. BROOK: What?

MS. RICHNER: What's the rush? I mean, why can't we all still be part of this in terms of the word smithing of the document?
DR. GARBER: I think the point is not -- if we were all in agreement that it is only word smithing, there would not be a problem. The whole issue is that what I think is word smithing, someone else might think is a major change. And I think we need to give other members of the Executive Committee

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an opportunity to review this.
DR. SOX: Well, wouldn't that end be served if we inserted an opportunity for members of the Executive Committee to look at the product after I have tweaked it, and if they object to any of the changes, then we'll have to find some way to get resolution.
DR. GARBER: I thought that's what I proposed.
DR. SOX: Well, but the only difference it that you (inaudible colloquy, several speakers) Bob -- the difference between your proposal and Bob's is that you would propose the working group get in the middle of it.
DR. GARBER: If you want to do it on your own, that would be totally fine from my point of view.
DR. SOX: Yeah, I'm happy to. I think Bob's suggestion is a good one and I can get it done pretty quickly.
DR. GARBER: But it's still -- where Bob and I disagree, it's not the issue of whether the working group sees it, it's that the entire Executive Committee have an opportunity to see it.
DR. BROOK: Well, we've all seen it.

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That's what we came to do here today.
DR. SOX: No, I think -- Bob, Alan's point is that people ought to get a chance to make sure that the word smithing changes don't destroy the intent of the document as we have approved it.

MS. RICHNER: The word sufficient for instance, versus adequate, but that's pretty major.
DR. SOX: Okay. We're going to move right around like this. Leslie?
DR. FRANCIS: I have a different kind of problem, which is that there is this entirely new section, pages 5, 6 and 7, which we haven't had a chance to sort of chew over as a group, and I mean, I'm very much in favor of the whole document. I think there's some ways that are substantive ways, they aren't just word smithing ways, that we could talk about what to do when the evidence is inadequate, and in particular I was worried about number one, dropping the idea of how do we think about a study that would take too long to do, how do we think about all the long-term kinds of problems, and that just gets dropped in here.
So I don't know when we'll ever have a chance to do that, and I just wanted to -- this is not in any way -- it's just that it's not word

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smithing, it's not to say in any way that we shouldn't go ahead with this, but maybe we should flag for our discussions at a later point some brainstorming possibilities about the new section.
DR. SOX: Well, I mean we have several options. You're proposing something that's going to take some grunt work, either now or later. You could make your proposal and we could vote it up or down, or you could just let it ride.
DR. FRANCIS: Obviously under the time, I think it's really important to just let it ride, but I wanted to flag for us that this is a section that we haven't had a chance to chew over and think about some of the kinds of issues that it raises, which -- I mean, I like it in general, but I think there's more we could say here that would be helpful.
DR. SOX: Do you want to respond to that point?
DR. GARBER: Well, I was just wondering if you were ready to entertain a motion yet.
DR. SOX: Well, there are a few other

people that had their hands up. I wanted to deal with them. Mike?

DR. MAVES: The only thing I would say is I think we would all welcome a written proposal with

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specific ideas and proposed language changes. I would also make sure, and I think this was brought up earlier, we would like to get Randel's outline. And I would also say to Randel, give us what you think is your proposed time line. It may well be that when that is down on paper it's not going to be something that's going to cause a lot of substantive argument and in fact, people may like it. I mean, that's one of the things that we didn't necessarily get today was what, if you don't like where we're at, where do you want to be, and if she gives that to us, we may well find that isn't a substantive change.

DR. BROOK: Can I try this one more time? Are we at the state with this document where we can vote it up or down and then add at the next meeting, we might have an hour discussion of amendments, which might include a time line, which might include looking at this section again, but I mean, it sounded like when we went around the room, everybody was -- and why don't we develop a process which we -- and I'm not even sure we ought to do word smithing on this document at the moment, because I believe that it will cause problems. I'm just wondering whether we should vote this up or down right now, send it out there, use it as guidance to the next panel that is

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planned, we come back in July, and the first piece of our agenda is to discuss amendments to the document. Why don't we do that, and if there needs to be work done between now and July, we ought to convene the methods subcommittee to do it in a formal way. Let's get this approved, since we have this in front of us, without word smithing, and don't change it, vote up or down at this moment, and then visit any amendments in July with the process to convene as a standing committee what the methods subcommittee has done to

the document in the next months.
DR. SOX: Do you want to make that as a motion?
DR. BROOK: I'll make it a motion. I move that we approve the document as such. I move that the methods committee becomes a standing subcommittee or whatever the heck the process is here, of the Executive Committee, and I move that people would like to have this document amended submit those concerns to the methods committee and that the methods committee prepares that as an agenda item for the next meeting.
DR. SOX: So, no word smithing, according to your proposal?
DR. BROOK: No word smithing.

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DR. SOX: No word smithing except to take into account the two major changes that we discussed.
DR. BROOK: The two word smithing that we've done right now, I mean the two changes we have done.
DR. SOX: So that's your motion, and that requires a second for us to act on it.
DR. HOLOHAN: Second.
DR. SOX: There's a second. Now we'll have discussion of that motion. Alan?
DR. GARBER: Actually I've kind of become sympathetic to what Bob is proposing except for the no word smithing bit. This document actually is technically not even what we had produced because it's gotten misformatted since it went, I think, between an IBM and Mac versions of Word. There's all kinds of little things that are small errors.
And I would like to propose to Bob aa friendly amendment, that this document, or -- it can't be amended because it's been seconded? But anyway, the amendment is minor word smithing that Hal can determine himself is truly minor, that should not change any substance of the document, and that we vote yes or no on the document that, subject to those truly minor changes, I think would be completely

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noncontroversial.

DR. SOX: And anything that I determine, any input that I got that seemed noncontroversial, I'm just going to put it aside for the next meeting.

DR. BROOK: That's correct.

DR. SOX: Would that be acceptable to you, Bob?

DR. BROOK: Yeah. You can clean up typos. I mean, my amendment should be, or the intended amendment is that anyone that has typos, formatting, plural versus non-plural, anything that, you know, you want to add a sense of what this clarifies, anything like that, let's deal with it. But other than that, it ought to be labeled as substantive and handled at the next meeting.

DR. SOX: Okay. And you have two weeks to get your input to me.

MS. RICHNER: One thing that you did the last time, Hal, that was helpful to me was that you essentially had it broken down by questions that were posed, and did anyone have comments on that, and that was very helpful. You took the document apart and said there's a question about this, what are your comments about it, and so perhaps if you could use that similar kind of format, that would be helpful

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for all of us to dissect this and provide our comments to you. I don't know.

DR. BROOK: I believe that we are doing word smithing and not substance. I would also like to argue that from now on, the substantive changes ought to be proposed to the methods committee and not the chairman proposing to the committee the substantive changes. That whatever substantive changes that the committee wants ought to be proposed to the chair of the subcommittee or the methods committee. This document is clear, it's clean, we ought to do that, and we ought to just move in a way and handle it in that way.

DR. MURRAY: Mr. Chairman, a point of order. I think we need a second for Alan's friendly

amendment.
DR. SOX: Yes. Do we, or is it sufficient just for the proposer to accept it?
DR. GARBER: The seconder has to accept it too, I think.
DR. SOX: Oh. Does the seconder accept it?
DR. HOLOHAN: Yes.
DR. SOX: Thank you. Any further discussion about Bob's proposal as modified by Alan?

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If not, I think this is something everybody can vote on. All in favor, raise your hand. Any opposed? Great.
(The vote was unanimous in the affirmative.)
DR. SOX: Well, in that case we have accomplished the second of our three tasks, and I am going to turn the meeting over to Sean to say a few remarks to sort of get us thinking in a constructive way about a process for dealing with the future of MCAC.
DR. TUNIS: This hopefully we can keep to, you know, five or so minutes. What we just passed around was a Section 522 of the Benefits Improvement and Protection Act of 2000, which I was just going to walk you through and give you a two-word summary of what's on each page so you know the things that relate to the coverage process.
So on the first page basically, this is just a new thing here, it's an item under iii that basically makes nation coverage decisions now appealable to a department advisory board, which is a body that exists within the Department of Health and Human Services. Previously, national coverage decisions had not been appealable to anybody and now

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they are appealable to this departmental advisory board, and we're sorting out how exactly that's going to work.
On the second page under local coverage

determinations, this allows for appeals of local medical review policies or local coverage decisions, which can be appealed to administrative law judges or they can actually be appealed, the decisions of the administrative law judges can also be appealed to the departmental advisory board. So they've introduced some more opportunities for beneficiaries to appeal local and national coverage decisions. There's also some provisions about, you know, under what circumstances manufacturers can or can't participate in asking for appeals.

On the third page, this actually puts in statute for the first time under Section 4 here, a 90-day clock. This is the first time this has appeared in statute, a 90-day clock for coverage decisions. At the end of 90 days, if you see the small letter, there's four items of what possible actions can be taken at 90 days, either a national coverage decision is issued, a national non-coverage decision is issued, we could issue a decision that no national policy will be issued, in other words, it

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will be carrier discretion or contraction discretion at the local level, and the fourth item is basically where we would not issue a decision but identify the remaining steps in the process and the deadline by which the decision will be made. So that's the, so in other words, that's something that can be determined at 90 days, but it has to come with an absolute deadline.

There's some debate internally about whether deadline means an actual date, or a deadline means based on a series of events that needs to occur, but it will probably end up being an actual date.

And then the last thing of most -- let's see. On the next page, it actually starts at the bottom of the previous page, about an annual report on national coverage determinations, item 7, this is what I mentioned before, that we will be required on a yearly basis by December 1st to give a detailed compilation of the actual time periods that were

necessary to complete and fully implement national coverage determinations. So that's a report to Congress.

In the next section under establishment of a process for coverage determinations, in the fourth

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line it says, the Secretary shall insure that the public is afforded notice and opportunity to comment prior to implementation. This is now a mandated opportunity for public input. What is somewhat unclear and we're sorting out is whether that means public input on a draft proposed national coverage decision, or this is public input during the, once the question has been identified, an opportunity for public input. As you can imagine, fitting all these things into 90 days is going to be an interesting challenge that we're trying to work out.

The next section, Section C, this allows for full participation of nonvoting members in the deliberation of the advisory committee, including access to all the materials. So in the point of adding members to the panels for content and methodological expertise, this just assures that they would have access to all the information that the full voting panel members would have.

And then the last -- the top of the next page, there's actually the key paragraph. It starts as number 2 on the previous page, and basically this says now that the panels of experts, in other words, our panels, may report any recommendation with respect to items and services directly to the

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Secretary without prior approval of the advisory committee or an executive committee thereof. This is the one that allows the panels to directly make recommendations to HCFA. Formally they are made, the formal language is they are made to the Secretary. So in other words, this gets rid of the notion of executive committee ratification as a necessary step in the process.

So, what I wanted to do was just mention

to you a couple of the thoughts that have been generated internally and some discussion with Hal and a couple of the other EC members about possible continuing roles for, what the implications of this might be for the executive committee and possible roles going forward. I'm not saying that they should be, I'm just throwing them out as suggestions for you all to think about until we meet again.

As we had discussed earlier, this says that the panels don't need to have their recommendations ratified, but it says nothing, it does not disallow the Executive Committee from discussing the recommendations made by the panels. And as we were talking about earlier, of having a detailed three to five-page summary from the panels explaining what the panel recommendation was just as

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we currently do, there is nothing that says that the Executive Committee couldn't and shouldn't comment on that and determine whether it's in compliance with the interim guidelines on methodology, et cetera, et cetera. And you know, if the Executive Committee wanted to even give a contrary view or suggest that HCFA send the thing back to the panel with some advice, the Executive Committee could do all those things. And I think, you know, probably some of that would be useful.

Obviously, the Executive Committee is going to continue to work with these interim guidelines for methodology as a continuing role, and that will obviously continue to occupy some time. Maybe one day they will be perfected, but it seems to me that those become increasingly important as the panels become more independent to create the conceptual framework and the evidence standards that the panels will be asked to apply and then obviously, the supervisory role of making sure that that happens would be a useful role.

The Executive Committee would seem to have an important role potentially in helping to frame the questions for assessment, as was discussed earlier, so early involvement in helping to make sure that the

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questions are being framed properly and then all the, again, as we discussed when talking about Randel's framework.

And then there are some overarching issues of coverage that come up, and I'll give you one that's quite current that we're struggling with related to PET, which we are not going to talk about today, but it has to do with whether the PET coverage policy should only be applied to the dedicated PET scanners, from which all the data was acquired, or whether that coverage policy should apply to coincidence cameras, which are gamma cameras that have been upgraded or outfitted to detect positrons in a coincidence mode, and I even hesitate to use this kind of language because it's so complicated I usually get it wrong, but basically it's pretty clear that the upgraded gamma camera systems for camera PET performs at some level lower than dedicated PET in terms of the quality of the images, the sensitivity, the specificity. There's no data that was ever submitted on the use of those cameras and we are now in a fairly intense discussion about how we're going to make this December 15th coverage decision apply and how broadly.

And it seems to me like a place, it would

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be nice to be able to come to a place like the Executive Committee and have that sort of overarching issue discussed. Randel just let out a sigh so maybe she doesn't agree. But they are complicated issues, and maybe that one's not a great example, but that sort of issue does come up. Did you want to say something, Barbara?

DR. McNEIL: I think that's a great example, to review and discuss it. There was actually an article in JAMA yesterday, I think, that was a synthesis --

DR. TUNIS: Yeah. It was on PET for pulmonary nodules.

DR. McNEIL: Yeah, PET for pulmonary

nodules. The data was pretty crummy, but it basically showed that there was no difference.

DR. TUNIS: Use of the gamma cameras versus the dedicated.

DR. McNEIL: Yeah, but they had only two gamma camera studies and 20 dedicated units, so it was really not a great comparison, but the data suggested no difference.

DR. TUNIS: And you will all be interested to know that the editorial for that article was written bi Ethan Balk and Joe Lowe, who were the

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writers of the Tufts report, and that's an interesting editorial.

DR. BROOK: Sean, I would just -- at some point we need to discuss what we mean by technology assessment, and like I said, we have taken this limited approach of your asking these questions which we have enough difficulty with obviously, but for instance, when a better angioplasty catheter comes up that costs three times as much, do we do another assessment of the older model and say that it's less -- since we don't do anything with costs, should you be asking us to do a lower assessment to produce the safety and health of the Medicare population to say that this is less good now than the other one, the evidence is in, this produces a higher complication rate, it produces more of whatever, and therefore, it would not be approved now.

So should we, as older technology exists that's being replaced -- as you know, there is 20 year time lags in some of this stuff or longer, and what should we do with the older and cheaper stuff that's not as good? So there's these kinds of fundamental questions. It would be nice to really have some understanding instead of us being on the receiving end of HCFA when they say this is what you

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want us to do, as opposed to us being on the proactive end to say this is how a technology assessment process ought to be run.

And how about open public discussion? We've never had that discussion with you all. I don't know whether it can be done in a public session, but that kind of discussion which would take advantage of our diversity and deal I think with Daisy's points of what our mission is here, is much different than the kind of discussions that we have had.

DR. SOX: Alan.

DR. GARBER: Well, on a different aspect of what you were mentioning, Sean, it's the ratification role that the Executive Committee has had and will no longer have. I personally never thought that the added value of the Executive Committee came so much from ratification as for providing feedback and helping to promote consistency among the different panels, and I think that everyone benefits from that kind of review.

As a panel chair, I appreciate getting the review by the Executive Committee and as I understand this, we give up the ratification role, but there is no prohibition on reviewing the panel's work and

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providing feedback. And I think that insofar as there's going to be some overarching common approaches to carrying out all the duties, the role of the Executive Committee is going to remain extremely important.

So, I would just like to suggest that I hope we continue to review the panel reports, the reasoning that the panels use to reach their conclusions, and provide feedback to the panels about how we think the process is operating. And industry may think that that's a bad thing; I would suggest it's actually to their advantage, because that's how we'll get consistency and uniformity across the deliberations of the panels, and everybody benefits if this is more predictable.

DR. FRANCIS: I think it might be useful to say that's a shared sentiment, at least from here. I don't know if others share it too, but we probably should indicate it if we do.

Ms. RICHNER: One of the things that I think maybe you can clarify, Sean, was that in BIPA, one of the suggestions was that you essentially write somehow a report, a memorandum, whatever, of what the coverage process is, and essentially what the process is, what it's supposed to be, what decisions are

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referred to MCAC and why, and what is the intent. I mean, those kind of things, if you could clarify that from your perspective, from HCFA's perspective, that might help a lot of this discussion along. And that's been one of our points, I think, that we have been floundering with for quite a while.

DR. TUNIS: No, actually I am not sure if that is in BIPA or if it's not, but in any case it is underway, we are planning to do a -- you know, we have a Federal Register notice that describes our process, you know, not every aspect of it, and we're certainly keeping now a tally of the sorts of things like what are the criteria for which something is referred to MCAC, which I think, you know, need to be spelled out, not that we have necessarily a great answer for that.

MS. RICHNER: And out of the thousands of decisions that are made every year, most of them are done on a local level. There's very few that come to the national level.

DR. TUNIS: Right, and those sorts of issues, it seems to me themselves would be useful issues to get some feedback from the Executive Committee, you know, what should the explicit criteria for referral of an issue to MCAC be. How

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should we be prioritizing, you know, given that we generate a certain number of internal assessments, you know, getting some feedback about the priority of a particular thing we might take on, I think would also be the kind of feedback we need.

MS. RICHNER: It would be very interesting to compare decisions that you've made at HCFA internally and what types of decisions are being

asked of our committee. I mean, if you posted all of your recent decisions, I think that would be very valuable for the committee to look at, what decisions you made and how you've gone about your process for those decisions.

DR. TUNIS: The last thing I was going to mention, it was going to be an item of some more detailed discussion if we could have done it, but I do think we're running out of time, but this sort of relates to helping frame the questions, but I think of it as sometimes there's questions about how to even scope an assessment topic and so as an example of this, we have agreed that we are going to be looking at the use of positron emission tomography for Alzheimer's disease. We are considering a number of approaches to that internally, one of which would be to look at the issue of neural imaging broadly in

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suspected dementia, so looking at CT, MRI and PET, not PET in isolation but in the context of alternative neuroimaging strategies.

Similarly, a critical part of the Alzheimer's question seems to be the existence now and in the future of potentially effective therapy and how effective is that therapy, and how effective is that therapy when it's started prior to even the manifestation of symptoms. But those sorts of scoping questions seem to me would be fair game for getting EC input, as opposed to making all of those determinations internally within the coverage group and then, you know, presenting you all a TEC assessment on PET for Alzheimer's disease. That's it.

DR. SOX: Well, I think trying to get the Executive Committee more involved in formulating an agenda for MCAC, that might not only address specific technologies but how you group them could be really valuable and it would be wonderful if part of our function would be basically to set the scope of work for the next year, and getting input from a varied group like this could be very useful and make things seem more predictable to everybody, you, us, as well

as industry.

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Well, I think unless there are further comments, we'll adjourn and give everybody best wishes for getting home. I need a motion.

DR. FRANCIS: I move to adjourn.

DR. GARBER: Second.

DR. SOX: Anybody object to disbanding at this point?

(The Executive Committee meeting adjourned at 12:05 p.m.)